

Impact case study (REF3)

Institution: Kingston University		
Unit of Assessment: 3 – Allied Health Professions, Dentistry, Nursing and Pharmacy		
Title of case study: Improvements to the procedures, capabilities and practices of the European Food Safety Authority and the UK Government Chemist Programme		
Period when the underpinning research was undertaken: 2007 – 2020		
Details of staff conducting the underpinning research from the submitting unit:		
Names:	Roles:	Periods employed by submitting HEI:
Declan Naughton	Professor, Associate Dean for Research	Aug 2005 – present
Adam Le Gresley	Associate Professor	Feb 2009 – present
Andrea Petroczi	Professor	Sept 2001 – present
Period when the claimed impact occurred: Aug 2013 – 2020		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact

Naughton, as sole academic member of the UK Government Chemist Programme Expert Group (GCPEG), made considerable contribution to the development, management and governance of four triennial GC Programmes on governance, research prioritisation, knowledge exchange, and horizon scanning to enhance food safety in the UK. As Chair of the External Review Working Group (ERWG), established by the European Food Safety Authority (EFSA), Naughton contributed to EFSA's continuous improvement programme with consequent reductions in food risk for over 500 million EU citizens. Through a series of interventions, the ERWG contributed to the total elimination of a considerable number of defects, which it had earlier identified in the majority (60%) of assessed EFSA Scientific Outputs and Risk Assessments.

2. Underpinning research

Naughton led and co-ordinated research, conducted at Kingston University (KU), concerning many key aspects of food safety and its regulation. These applied studies led to his invitation to join - and supported his role as the lead academic on - the UK's GCPEG from its inception in 2009, until 2021. The research also underpinned his contributions to the ERWG, which was established by EFSA in 2009 to enhance the quality of its scientific outputs in areas covered by EFSA's Scientific Units, its Scientific Committee and Advisory Forum Unit. The research covered two areas:

i) Development of novel computational approaches to interrogate vast food safety databases to inform regulatory bodies

At KU, Naughton's group studied global food safety datasets to inform risk assessments and enhance food safety measures. Their work developed and applied novel, advanced computational Network Analysis Tools (NATs) that permit the detection and analysis of information in complex databases. These tools were used to identify contribution of states as transgressors (producers of unsafe foods) and detectors (of unsafe foods) by instantaneous interrogation of the data. This analysis of the data identified clusters of transgressor states informing regulatory enforcement measures to target key players. In addition, they revealed underlying trends, which were inaccessible through descriptive statistics [R1].

The NATs underpinned wide-ranging studies of direct relevance to food safety policy-makers and regulators. These included demonstrated the wide variation in the quantity and type of reports of faulty foods between Member States in their contributions to the EU Food Safety Database [R2]. The NATs provide a unique and timely tool for instantaneous interrogation of continental food safety databases, enabling regulators to monitor transgressors and detectors on a daily basis, and to determine emerging issues and hidden trends in reporting.

ii) Development and application of modern analytical methods for food safety and public health

The effective development and application of modern analytical methodology is a cornerstone of food safety and its regulation. Through his research at KU, Naughton has spearheaded the application of several analytical approaches, developing advanced methods of relevance to food safety and public health. Using techniques such as High Resolution Nuclear Magnetic Resonance (NMR) Spectroscopy and Liquid Chromatography Mass Spectrometry (LC/MS/MS), Naughton produced methods including:

- An advanced lipidomics study of cooking oils which applied resolution NMR to formulate a strategy to reduce genotoxic and cytotoxic lipid oxidation (where polyunsaturated fatty acids react with oxygen to produce toxic by-products) products during cooking [R3].
- A novel LC/MS/MS based vitamin D assay was developed – to include vitamin D epimers and disregard interferents – which revealed that most previously studies relied on measurements that were not fit for purpose. The advanced assay, with the capability of accurately measuring ten forms of vitamin D, led to novel capabilities to study the roles of vitamin D forms in childbirth, health, and serious diseases [R4].

Naughton's research also developed advanced methods to:

- determine over 200 social and performance-enhancing drugs (and their metabolites) in a single analysis of a hair sample for forensic and anti-doping tests [R5],
- conduct a UK National Prevention Research Initiative Phase 4-funded intervention study using the in-house multi-drug hair test to determine adherence to healthy life choices among university students [R6],
- develop scanning microscopy methods to study diet-induced tooth decay [R7].

Expertise in developing advanced assays, applying state-of-the-art facilities, data mining and risk assessments underpinned Naughton's contributions to the EFSA ERWG and the UK GCPEG.

3. References to the research

R1 – Nepusz T, **Petróczi A**, **Naughton DP** (2008) Worldwide food alert patterns over an eleven month period: A country perspective. BMC Public Health, 8(308), 1-9, DOI: [10.1186/1471-2458-8-308](https://doi.org/10.1186/1471-2458-8-308)

R2 – Taylor G, **Petróczi A**, Nepusz T, **Naughton D** (2013) The Procrustean bed of EU food safety notifications via the Rapid Alert System for Food and Feed: Does one size fit all? Food and Chemical Toxicology, 56, 411-418, DOI: [10.1016/j.fct.2013.02.055](https://doi.org/10.1016/j.fct.2013.02.055)

R3 – Percival BC, Wann A, Zbasnik R, Schlegel V, Edgar M, Zhang J, Ampem G, Wilson P, **Gresley AL**, **Naughton D**, Grootveld M. (2020) Evaluations of the Peroxidative Susceptibilities of Cod Liver Oils by a 1H NMR Analysis Strategy: Peroxidative Resistivity of a Natural Collagenous and Biogenic Amine-Rich Fermented Product. Nutrients, 12(3). pii: E753. DOI: [10.3390/nu12030753](https://doi.org/10.3390/nu12030753) REF2ID: 03-127-1883

R4 – Shah I, **Petróczi A**, **Naughton D** (2014) Exploring the role of vitamin D in type 1 diabetes, rheumatoid arthritis and Alzheimer's disease: new insights from accurate analysis of ten forms. The Journal of Clinical Endocrinology & Metabolism, 99(3), DOI: [10.1210/jc.2013-2872](https://doi.org/10.1210/jc.2013-2872)

R5 – Shah I, **Petróczi A**, Uvacsek M, Ranky M, **Naughton DP** (2014) Hair-based rapid analyses for multiple drugs in forensics and doping: application of dynamic multiple reaction monitoring with LC-MS/MS. Chemistry Central Journal, 8(73), DOI: [10.1186/s13065-014-0073-0](https://doi.org/10.1186/s13065-014-0073-0) REF2ID: 03-147-1078

R6 – Epton T, Norman P, Dadzie A, Harris PR, Webb TL, Sheeran P, Julious SA, Ciravegna F, Brennan A, Meier PS, **Naughton D**, **Petróczi A**, Kruger J, Shah I (2014) A theory-based online health behaviour intervention for new university students (U@Uni): results from a randomised

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controlled trial. BMC Public Health, 14(563), DOI: [10.1186/1471-2458-14-563](https://doi.org/10.1186/1471-2458-14-563)

R7 – Hookham M, Lynch R, **Naughton DP** (2020) Characterisation of mineral loss as a function of depth using confocal laser scanning microscopy to study erosive lesions in enamel: a novel non-destructive image processing model. Journal of Dentistry, 99, 103402, DOI: [10.1016/j.jdent.2020.103402](https://doi.org/10.1016/j.jdent.2020.103402)

All publications are in international peer-reviewed journals and were well received by other researchers in the field; **R5** and **R6** related to an MRC grant of GBP489,754 (MR/J0004501/1).

4. Details of the impact

Through his work with the Government Chemist and the European Food Safety Authority, Naughton's research has had an impact on the practices of both these institutions, and has benefitted citizens in the UK and Europe, as a result of improved food safety.

Supporting the Government Chemist Programme to improve its statutory function covering public protection, safety and health, value for money and consumer choice

From its world-leading position, the UK Government Chemist (GC) provides input, advice and opinions on ongoing areas of concern such as exiting the EU and developing gold-standard analytical methods to address issues such as genetically modified organisms (GMOs), allergens, mycotoxins and horsemeat in the food chain. The GC also acts as referee analyst in disputes between regulators and industry – such as when large food cargo consignments are denied entry at ports and when toxin analyses are disputed.

The GCPEG - an independent panel of experts drawn from industry, enforcement agencies and academia - guides the work of the GC by providing independent scrutiny, overseeing the delivery, planning and quality of the programme, and offering advice to BEIS regarding future priorities and the strategic direction of the programme [S1]. Biannual GCPEG meetings function to consult on: (1) The effectiveness and impact of the Programme in providing an independent, expert service for food control authorities and industry; (2) progress of current projects in meeting technical milestones and targets; and (3) the formulation and prioritisation of new projects to maintain and develop the capabilities needed to discharge the Government Chemist functions.

Each triennial programme (costing approximately £1.1 million per year) is devised following a comprehensive stakeholder consultation to identify the most important issues (projects) in food regulation [S1]. This process has led to over £10 million investment in facilities and the development of expertise and preparedness for emerging and ongoing demands. Since 2013, the capability-building programme has led to better practice in many key aspects of food safety – including detection of contaminant species (e.g. horsemeat), advances in allergen and mycotoxin detection, food authenticity tests, detection of contamination with nanoparticles and illegal dyes, mislabelling and GMOs.

Naughton has been a member of the GCPEG since its inception in 2009. advising on, and providing stewardship for, four triennial Government Chemist Programmes. He is the sole academic member, bringing specialist expertise - a direct result of his research conducted at KU – in: (1) advanced analytical measurement; (2) food safety database interrogation/horizon scanning; and (3) nutrition/toxicology/public health. This research is instrumental in providing expert advice on priority areas of development within the GC Programme and assessing their progress. The research developed at KU was included in the GC programme and supported by a Food Standards Agency Award. The Network Analysis Tool for food safety – developed entirely at KU (2008-2014) – was incorporated into the GC programme to evaluate the needs of global stakeholders to interrogate extensive food safety databases in real time [S1, S2, S3]. This tool provided important knowledge of: (1) unseen trends within food safety databases within the EU and worldwide; (2) a clear rapid report on horizon scanning of growing issues with nations producing risky foodstuffs; and (3) the key priorities of global stakeholders (predominantly National Food Regulatory bodies) [S1]. The Deputy Government Chemist commented that

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'Professor Naughton's provision of access to a novel innovative network tool was key to winning a research bid from the Food Standards Agency to conduct a global stakeholder consultation on the tool and what the crucial components of any food early warning system should be.' [S4]

Naughton has also led on informing the GC on ways to enhance stakeholder participation. This led to a four-fold increase in knowledge transfer *via* journal publications and conference papers [S2, S5] and thus has expanded engagement among stakeholders worldwide. Examples from the latest triennial Programme include research-underpinned expert support for the GC's major capability building strands (i) rapid, non-targeted multi-analyte approaches [R3, R4, R6], and (ii) advanced methods for mycotoxins [R4, R6], along with Statutory Function-Infrastructure & Quality and Horizon Scanning [R1, R2].

The Government Chemist appointed Referee Analyst commented on Naughton's *'cutting edge research'*, saying *'the GPEG, and thus the Government Chemist Programme itself, have benefitted considerably, in particular, from your valuable insights into research prioritisation, knowledge exchange and horizon scanning. Your scrutiny and advice contribute to ensuring our science and contextual awareness continue to be of the highest standard'* [S4]. The Government Chemist commented *'I am grateful to Professor Naughton for his advice and guidance on the Governance of the discharge of my function and his contribution to increasing the rigour of our research. Sound governance is crucial to demonstrate our independence to food industry regulators, industrial stakeholders and the courts'* [S4].

Reducing errors in scientific outputs and improving quality management for EFSA

EFSA was established in 2002 – following a series of food crises - as the main European body providing scientific advice and communication on risks in the food and animal feed chains. Producing Risk Assessments is its main activity, for which it has some 450 staff and an annual budget of around €50 million. These Risk Assessments are used widely by legislators, regulators, producers, industry and consumers throughout the EU and globally. EFSA established the ERWG in 2009 to review the quality of its scientific outputs in areas covered by EFSA's scientific units, its Scientific Committee and Advisory Forum Unit.

The ERWG contribution, with significant leadership from Naughton and scientific contributions based on his research, led to a marked increase in the quality of scientific risk assessments along with a move from a quality control to a quality assurance approach. Considerable increases in quality were instilled in EFSA activities with each annual review, which consisted of multiple recommendations that were mostly enacted by EFSA. The magnitude of improvements is reflected in a large increase in assessed Risk Assessments and Scientific Outputs receiving the highest quality scores - for being well constructed, transparent, and easily understandable. This enhancement is reflected in the move from only 40% of assessed scientific outputs scored as of very high quality in 2011. This, according to an external evaluation by Ernst and Young, and to the EFSA Quality Manager, rose to 100% in December 2014 [S6, S7]. Thus, all serious flaws in Risk Assessments and Scientific Outputs were eliminated and confirmed through three annual reviews by the ERWG (up to December 2014). This improved standard has been maintained through to the latest quality report in 2018 [S8]. Extensive changes to practices and procedures included:

(1) The systematic improvement of the quality of EFSA scientific outputs leading to the eradication of erroneous outputs.

Provision of risk assessments and scientific outputs is the major role of EFSA. The ERWG Review, in December 2013, made 12 recommendations advising EFSA to: (1) move from quality control to quality assurance procedures; (2) further implement project management procedures to drive accountability and responsibility along; and (3) through a cluster of recommendations, optimise the editorial processes for producing rigorous Scientific Outputs. The recommendations were accepted leading to the elimination of significant errors in EFSA outputs assessed in the ERWG Review in 2014 and 2015 [S7].

The response from EFSA to the ERWG Report (2014) stated *'The ERWG found the scientific outputs of EFSA to be of a very high standard. Over the past 3 years the quality of EFSA's outputs can be shown to have improved and for the first time this year the ERWG has made no*

recommendations with regard to improving EFSA's own outputs. The main recommendation from the group is for EFSA to fully implement a QMS based on quality assurance.' [S7]

(2) Proposal for a new procedure for procurement of external third-party technical reports which inform EFSA risk assessments and scientific opinions.

The ERWG Review, in 2014, was extended to examine a broader range of EFSA activities. A set of recommendations were implemented to adopt a rigorous project management approach for commissioning and accepting external technical reports to improve the quality of third party reports commissioned to enable delivery of higher quality EFSA outputs. The EFSA Quality Manager wrote *'The recommendations from the report focus this year on the need to continue making progress on the development of a QMS based on quality assurance and the need to improve the quality of third party reports.'* He explained how *"the ERWG formed four specific subgroups (EFSA Journal, Quality Assurance, Alignment of ERWG and DG SANTE customer feedback criteria, and Quality of third party outputs. ... the group on quality assurance identified the key steps in the process scientific where we can have an impact on the quality of the outputs, thereby contributing to the development of a quality assurance system.'* [S7]

(3) Adoption of a Quality Management System to ensure effective working arrangements.

The ERWG Reviews of 2013 to 2015, made recommendations leading to the establishment of a project management co-ordination office to implement a project management approach. A detailed QMS was proposed by the ERWG as part of its remit in 2015.

The response from EFSA described that *'The External Review Working Group (ERWG) gave a first positive feedback to the new Quality Assurance System for Science'* and that *"An in-depth review of the system is being performed by the ERWG"*. *"The ERWG provided very positive feedback on this new system. EFSA will build on this review and fully implement the new system by mid-2016"* [S7].

The work of EFSA has greatly improved – in particular for those relying on authoritative Risk Assessments and Scientific Outputs. This directly affects food safety in the EU, impacting positively on the daily lives of over 500 million citizens, and also influences policy in countries outside the EU. EFSA answers some 700 formal questions per annum, mainly arising from the European Commission, Member States and industry. These questions assist with a range of functions including risk assessment, informing new laws and the licensing of new food constituents. The attainment - in 2016 - of the international standards organisation's ISO 9001:2015 was a major milestone. EFSA was then audited in 2018 by the certification body, who concluded EFSA's Quality management is robust and fit for purpose [S8]. As evidenced by its performance, and its recognition by standards bodies, EFSA has significantly improved its processes.

The contributions to the GCPEG and EFSA derive directly from Naughton's research expertise, and have led to lasting enhancement of performance and capability for each organisation.

5. Sources to corroborate the impact

S1 – Government Chemist Publications (Strategy, Annual Review, Review), 2014-2020

S2 – [GC Press release](#) (2017)

S3 – Data mining tool to address safety of imported food including identification of emerging risks. A collaborative project funded by the Food Standards Agency (FS204011)

S4 – Testimonial by the Government Chemist, Deputy Government Chemist and Government Chemist appointed Referee Analyst.

S5 – This increased activity is exemplified by the award of PhD by Publication by Kingston University for the GC appointed Referee Analyst in 2017 with Prof Naughton as advisor.

S6 – External Evaluation of EFSA, Final Report, Ernst and Young. (p 38)

S7 – EFSA Annual Quality Managers Reports, 2014 & 2015

S8 – EFSA Consolidated Annual Activity Report, 2018. (p 79)