Assessing a national nanotechnology infrastructure for enforcing nanosafety in consumer food - Funding the infrastructure

E McCarron1,2 and G Chambers1
1 Nanolab research centre, FOCAS Institute, Technological University Dublin, Ireland
2 State Laboratory, Young’s Cross, Celbridge, Co Kildare, Ireland
E-mail: Eileen.McCarron@statelab.ie

Abstract. Crucial to assessing any national risk assessment infrastructure is the development of keen insights into the funding landscape, the base skill set and expertise levels, risk prioritisation, and stakeholder determination. This paper presents an overview of the first of these criteria with respect to the Irish funding landscape for nanotechnology and nano-agri-food. It examines difficulties with policy enforcement due to a lack of clarity and varying interpretations of the EU definition of nanomaterials and how the funding landscape could potentially facilitate the necessary infrastructure, to underpin regulatory enforcement and risk assessment for nanotechnology in food. In 2008 an assessment of the potential risks associated with nanotechnologies was carried out in Ireland which resulted in a number of recommendations centred around the provision of funding. This study examines Exchequer/public investment over the last decade to develop research infrastructure and it identifies if such investment has helped enhance the enforcement of nano-food safety legislation in Ireland.

1. Introduction
Over the coming decades the agri-food sector will need to adapt to meet many challenges in relation to demand, production and distribution of food [1, 2]. Nanotechnology has the potential to positively impact and address some of these challenges. While it is recognised that applications of nanotechnology in the agricultural sector, may offer potential benefits, there is also concern that some nanomaterials may present unidentified hazards. A number of expert groups at National, European and International level have issued opinions on applications of nanotechnology in the food sector [1–6]. These opinions share common themes with respect to identifying potential safety concerns and knowledge gaps in the use of nanomaterials and nanotechnology in the food sector. Specific concerns centre around the toxicological, physiological, and environmental effects of nanomaterials. In particular the European Food Safety Authority (EFSA) noted that risk assessments approaches and available methodologies pose significant challenges in adequately identifying the potential risks of nanomaterials in food and feed [7].

As a consequence, EFSA have published scientific guidance documents for risk assessment agencies and national competent authorities to help assist the evaluation of nanotechnology in the food chain [2]. The European Union (EU) has also funded numerous research projects to support the risk assessment of nanomaterials. Examples of such projects include FP7 nanoimpactnet [8], NanoDefine
[9] etc. many of which aim to essentially provide guidance frameworks to help standardise analytical methodology and measurement criteria for nanomaterials. Indeed the results of some of these projects have helped shape EU regulation governing the authorisation and regulation of nanomaterials within different sectors. In the agri/food/feed sector some EU regulations refer specifically to nanomaterials, providing details regarding approval procedures, safety assessment, labelling requirements and in some cases a definition of nanomaterials e.g. the Novel food regulation (EU) 2015/2283 [10], the Plastic food contact materials regulation (EU) 10/2011 [11], the Food Information to Consumers Regulation (EU) 1169/2011 [12], the Food Additives Regulation (EC) 1333/2008 [13] etc. The REACH regulation, for the registration, evaluation, authorisation and restriction of all chemicals (REACH (EC) 1907/2006) [14] while not directly related to food/feed also considers nanomaterials. In 2018 changes to the REACH regulation were enforced by the EC to address nanoforms of substances, the changes came into effect in January 2020. However, the regulation has been met by legal appeals on compliance checks and on substance evaluation decisions, many of which stem from a lack of guidance on the EU definition of nanomaterials which was used to underpin the REACH regulation. Furthermore a number of EU Member States have undertaken independent substance evaluation reviews on nanomaterials, for example Titanium Dioxide (171) - 2015/19 (France) [15-16], which has called into question the validity of the EU risk assessment process that underpins the legislation. A key question therefore is how risk assessors and competent authorities can maintain pace with the changing analytical requirements of new and evolving legislation which demands increasing levels of complex analysis.

The work reported in this paper is part of a larger study examining Ireland’s capacity to meet these challenges and to assess the implementation of recommendations made a decade ago by the Food Safety Authority of Ireland (FSAI) [5]. In 2008, the FSAI carried out an assessment of the potential risks associated with nanotechnologies in the food and feed industries of Ireland [5]. The assessment outcome raised concerns over the safety of nanomaterials and the lack of regulatory controls at the time. It also strongly recommended the need for a coordinated approach to the allocation of funding across Government Departments and Agencies, to support the national nano-infrastructure with an emphasis on method development for the regulatory control of nanomaterials. This paper explores national research funding from Exchequer/public funding from 2008 to 2018. It attempts to assess if the recommendation of a financial commitment to build human capacity and the infrastructure necessary for risk assessors to maintain strong regulatory enforcement of nanomaterials in the agri-food sector has been delivered upon. A key focus will be to identify the percentage of total funding support made available for ‘nano’ research and the subsequent percentage capable of supporting the infrastructure necessary for nano-risk assessment method development.

2. Methodology
Data collection consisted of three processes: review of Exchequer policy documents and reports, direct communication with relevant Government Departments and an in-depth review of the Exchequer funding databases to determine how much money was allocated towards research projects, equipment and associated facilities, training, and other related activities.

The initial collection of data focused on obtaining information from policy documents, and reports produced by Government Departments and Agencies. This information, was freely available on Government websites. Relevant documents and reports were selected for comprehensive review based on a step wise approach to data mining involving keywords searches and cross referencing [17]. Table 1 gives a representative list of keywords used. A total of 28 words were used and to reduce this down cross referencing was used. This facilitated the identification of the key documents for in-depth review and the qualitative analysis of documents pertaining to Exchequer investment in nano-specific projects capable of supporting regulatory enforcement.
Table 1 Representative list examples of keywords used for data mining.

| Nanotechnology | Nanoscale | Food/foodstuff | Food packaging | Nanodevice |
|----------------|-----------|----------------|----------------|------------|
| Nanoscale properties/phenomena | Manufactured nano | Nanospecific method | Nano manipulation | Size determination |
| Nano-scale measurement techniques | Nano-encapsulation | Food production | Engineered material | Food contact material |

As a follow up to the aforementioned review, direct interviews with individuals with responsibility for administering funding/supporting policy and regulation were carried out, as well as a preliminary/ongoing survey of academics. The interviews focused on discussions around funding calls in the period 2008-2018. These individuals provided additional qualitative and/or quantitative information, to date more than 50 Principle Investigators from academia have responded to the survey and several interviews have been carried out. The data, to date, from both the survey and interviews have been encoded and statistical analysis was performed using Microsoft Excel [18].

Finally Exchequer funding which was allocated towards research projects, equipment, facilities, training, etc. was assessed using the relevant funding agencies databases for the period 2008-2018. This provided elements and snapshots of the outcomes of the funded projects, including research infrastructure acquired and other relevant activities. The process involved identifying who or where (Academia Institution/State Body) received Exchequer funding in the period 2008-2018. It also identified the purpose of the funding, (e.g. equipment, facilities, research infrastructure/grants, training etc.). The data was analysed and categorised to identify which elements of the funding was specifically directed towards establishing research infrastructure that could underpin the regulatory process. It was further subdivided into funding which was directed towards the agri-food sector with a ‘nano’ related theme. Much of the data was supported and cross-referenced with accessible evaluation reports from Department/Agency level which was publically available on Government/Agency websites these included annual accounts, and/or annual output statements.

3. Results

A review of Ireland’s Gross Expenditure on Research and Development (GERD) indicates that approx. €29 billion was directed towards research and development (R&D) over the period 2008-2017 [19]. The main source of funding was from business enterprises accounting for almost 50%, while direct Government funding contributed approximately 30%. International sources e.g. the European Commission, and private not for profit organisations contributed 22% of the total funding. Direct Government R&D Funding (30%) as measured by the ‘Government Budget Allocations for R&D’ (GBARD) can be prioritised by Government Departments and Agencies for the purpose of R&D to build capacity and infrastructure of importance. This public or Exchequer funding is normally made available through research funding bodies from open research calls aligned to national priorities [20]. For the period 2008-2017 more than €8.7 billion was made available for such research funding through this mechanism. Examples of Agencies and departments with responsibility for the distribution of these funds is shown in figure 1 and represents the main public research funding Agencies in Ireland.
Enterprise Ireland (EI) and the Industrial Development Authority (IDA) are State Agencies who are responsible for supporting Irish businesses with strong R&D programmes underpinning their activities, helping them at start up, to expand and to enter global markets. Significantly these Agencies can provide Exchequer funding to support infrastructural development through collaboration between industry and research institutions. As shown in figure 1 these Agencies constitute almost 49% of Exchequer research funding. The remaining 51% of Exchequer funding committed to building Ireland’s research infrastructure and resource capacity within the ‘public/state’ sector is distributed through Science Foundation Ireland (SFI), the Department of Agriculture Food and Marine (DAFM), the Department of Education and the Higher Education Authority (HEA) as detailed in figure 1. This investment is dedicated to funding R&D in Higher Education Institutes (HEI’s) providing facilities, equipment, resources and services, and to maintaining research centres. SFI, the largest Exchequer funding Agency aims to promote study and engagement in the areas of science, technology engineering and maths (STEM). Exchequer funding directed towards SFI activities from 2008-2018 amounted to €4.2 billion. A review of the breakdown of funding over that period shows that approx. €95 million (2.2%) of the total SFI funding was referenced as ‘Nanoscience/Nanotechnology’ – comprising: approximately 90% Information Communication Technologies (ICT) and 10% biotech, medical, and pharmaceutical. The data as shown in figure 1 indicates that SFI was the leading funder of nanotechnology led research in the State for the period under review. In contrast, food based research and infrastructural supports for the agrifood research sector are predominantly funded by the Department of Agriculture Food and the Marine (DAFM), which accounts for approximately 5% of the total Exchequer research funding. It should be noted that the other Agencies do fund overlapping disciplines and support transferable infrastructure, however it is not their primary focus. Research funding from Exchequer sources in areas related to agricultural science is significantly lower than for any other fields of science. Data from the Central Statistics Office (CSO) indicates that the consistently low level of funding for this research area is approx. €20 million/pa, or 3% of total research funding since 2006 [21]. This in itself is surprising since the agri-food sector in Ireland generates an average of 7% of the country’s gross value added per annum.

A review of an Irish institutional repository of research activities (rian.ie) was carried out to obtain information relating to research activities that were specifically referenced as ‘nano’. The search period criteria extended from 2008–2018. Figure 2 represents the main research activity focus, relative to search terms for ‘nano’ related activity. The figure illustrates a broad overview of ‘nano’ research activities across all institutions which clearly indicates that nano-agriculture/food, risk and characterisation/instrumentation comprises only approximately 10% of all ‘nano’ related research in the Higher Education Sector.
A breakdown of institute activities based on repository data also reflects the trend in figure 2 as displayed in figure 3. Figure 3 clearly indicates a significant deficiency of ‘nanofood/risk based research’ that could potentially support method development for legislative purposes and/or deliver the infrastructure to underpin enforcement in the nano-food area. This is unsurprising since all but one of the listed organisations are Higher Education Institutions (HEI’s) with broad remits of research and minimum engagement with competent authorities for State risk assessment. Outside of HEI’s the Agriculture and Food Development Authority in Ireland (legally referred to as Teagasc) is the leading performer of R&D in the agrifood sector. Teagasc is a Government sector body providing integrated research, advisory and training services to the agriculture and food industry and rural communities in Ireland and is primarily funded by the Department of Agriculture Food and the Marine (DAFM). As a result it has great potential to support the infrastructural and expertise needs of State laboratories and Agencies engaged in regulatory enforcement of nano-food. It should also be noted however, that there is significant overlap in skillsets between the categories listed in the legend of figure 3, and so the potential for knowledge transfer from academia to national risk assessors is also present.

Figure 2. Research activities specifically referenced as ‘nano’ by research focus.

Figure 3. Nano Research activities: Research Institute and research focus by discipline.
To further investigate the potential for knowledge transfer from academia a preliminary survey of academics from different HEI’s was carried out and is ongoing. The preliminary survey to date has engaged with more than 50 respondents. While most respondents indicated that they believed they had the technology available to measure nanoparticles in the institute’s laboratory environment, only 25% of those surveyed believed that they had the analytical infrastructure available to ‘fully characterise applications of nanotechnology in the agri-food sector’. Additionally only 38% of respondents believed that the infrastructure was available nationally. An interesting point which was highlighted during interview discussions, was the academic’s opinion that “the skillset is there (in academia) from a general point of view of characterizing nanomaterials, but in terms of using the skills, in the context of food, and nanofood there may be a need for up-skilling’. Indeed this notion seems to agree with the data presented in figure 3, which does indicate that the basic skill set is available nationally, but is not nano-food or nano-risk specific. Furthermore the preliminary data indicates that nanofood risk assessment is not a priority for academic based researchers.

In contrast 77% of interviewees from national risk assessment Agencies indicated that developing a national nanotechnology testing capability is a priority, or that it will be within the next five years. Worryingly 92% of these respondents are not confident that they have the available resources i.e analytical capacity/skilled personnel to support nanotechnology testing procedures, nor are they confident that the existing legislation/regulatory framework is sufficiently evolved to support potential nanotechnology testing plans. It should be noted however that the data is preliminary and is from a small sample size estimated to be about 25% of those engaged at a senior level in nano-food risk assessment.

4. Discussion

The safe implementation and incorporation of nanotechnologies into consumer goods raises a number of concerns due to knowledge gaps with respect to human and environmental exposure risks associated with nanoparticles [2, 5-7]. This knowledge deficit is a particular concern in the food sector where a number of factors such as the lack of clarity in the legislative terminology of ‘Nano’, the natural evolution of traditional food processing techniques and the potential of nanotechnology to enable novel food technologies have combined, to significantly increase the potential for public exposure to nanomaterials. A key question surrounding these issues is ‘how can the regulatory community begin to address the knowledge gaps in the risk assessment of novel nano-food products to help enforce new nano-specific legislation’? In 2008, the Food Safety Authority of Ireland (FSAI) carried out an assessment of the potential risks associated with nanotechnologies in the food and feed industries of Ireland [5]. Around the same time EFSA also issued an opinion on the safety of nanomaterials [6]. Indeed over the years many national and international reports have reinforced the need for research to identify the potential risks of engineered nanomaterials to human health and the environment, as well as calling for the development of new test methods to unambiguously characterise and elucidate the risks posed by nanomaterial inclusion in food products [2, 3, 5-7]. Some common thematic recommendations drawn from these reports include the need for:

- Greater communication and co-ordination within and between the various risk assessor organisations and greater collaboration with the wider scientific community.
- The development of a centralised, maintained, searchable repository of information on nanoparticles and test methodologies.
- Urgent and detailed consideration of the instruments needed to address concerns and challenges assessing the health and environmental safety concerns of manufactured nanomaterials.
- Information and advice on handling/using nanoparticles,- sample preparation for human and eco-toxicology testing; dose measurement and metrology.
- The need for research funding prioritisation to develop nano-risk assessment methodologies and to help underpin the regulatory process.
The main focus of this paper is the latter recommendation in the context of Ireland’s agri-food sector and Exchequer/public research funding allocation in the period 2008-2018. The FSAI report was published more than a decade ago, during which time more than €29 billion was directed towards research and development in Ireland [19] of which almost one third was from direct Exchequer funding sources. In the same period Irish agri-food sector exports have increased by 73% from €7.8 billion in 2009 to €13.7 billion in 2018 [22]. Indeed the agri-food sector is Ireland’s most important indigenous industry playing a vital role in Ireland’s economy. In terms of exports the agri-food sector is second only to the pharmaceutical sector and is constantly placed ahead of other manufacturing sectors such as the ICT sector. As indicated in the results, research funding from Exchequer finances in areas related to agricultural science is significantly lower than for any other field of science. Figure 4 presents a typical breakdown of research activity by field of science in Ireland, which further reinforces the notion of a reduced research capacity in the agricultural sciences field with only 3% of the total activity.

![Figure 4. Breakdown of research activity by field of science (2016 Headcount figures).](image)

The consistently low level of funding for this research area i.e. approx. €20 million/pa, undoubtedly reduces the dedicated infrastructural capacity and support expertise available to regulatory bodies and national risk assessors for emerging areas of concern such as nanotechnology. Much of the shortfall in funding for applied research in the agrifood sector is made up by corporate or business sector funding which often comes from corporations self-funding research, or engagement in collaborative ‘matched’ funding schemes with public sector bodies such as Teagasc the Agriculture and Food Development Authority. The Irish Government have invested €86.5Million in such schemes through the Knowledge Transfer Ireland (KTI) initiative which supports industry-academia research collaborations [23]. Nevertheless, the focus of such programmes is often on the aims and objectives of the industry partner as opposed to any national risk assessment agenda. Significantly such schemes do provide an avenue for the development of important research expertise and trained personnel, which could play a role in supporting the development of new methods for risk assessment.

The nanospecific infrastructure capacity in Ireland has largely been established in the University sector, through Exchequer funding. The predominant nano-research areas funded nationally include nanomaterials and characterisation, devices and technology. This reflects much of Ireland’s multinational landscape, with large ICT, medical device and pharmaceutical corporations based on the island. This has therefore evolved a competent academic community of researchers and infrastructure, suggesting that the skillset is available to help national risk assessors who are engaged in the enforcement of nano-specific legislation. It is acknowledged that some degree of up skilling would be required to adjust the expertise to meet the needs of the nano-agrifood sector. A significant disadvantage however with respect to the infrastructure, is the need for accredited laboratories facilities. Many of the academic laboratories funded by the Exchequer are research laboratories or centres and are not
accredited facilities. This was reflected in interview and survey responses, in which regulators acknowledge that the capacity is probably there, but not in an accredited laboratory for that specific purpose and so there is a reluctance to collaborate with academia’. It is therefore evident from the results of the funding assessment that the infrastructural needs and expertise required to enforce nanosafety legislation in consumer food is present on the island and that the national funding strategy over the last decade has created the required infrastructure. However issues of accessibility to the risk assessment community and the need for accredited facilities remain. It is imperative moving forward that greater communication and co-ordination is developed between the various risk assessment organisations and the wider scientific community, in order to take advantage of the infrastructure and expertise that have been put in place by a decade of research funding.

At EU level a similar approach is been taken with respect to a strategic approach to the assessment of emerging contaminants of concern in the ‘Horizon Europe Partnership for the Assessment of Risk from Chemicals (PARC)’. PARC is an EU-wide research and innovation programme to support EU and national chemical risk assessment and risk management bodies with new data, knowledge, methods, networks and skills to address current, emerging and novel chemical safety challenges, one of which is nanomaterials [24]. Implicit in the concept of PARC is the open and direct communication by all stakeholders from academia through to the competent risk assessment bodies at national and subsequently at EU level. If Ireland seeks to engage in such a programme it is imperative that the next stage of its nano-risk assessment strategy in the agrifood sector and/or other areas focuses on developing a national forum for risk assessment, to align agendas and to facilitate knowledge transfer and engagement between all risk assessment stakeholders.

5. Conclusion
This paper presents an overview of the Irish research funding landscape and how it was utilised to help develop national capacity and infrastructure to underpin nano-risk assessment in response to recommendations from the Food Safety Authority of Ireland and other international reports. It is clear that the recommendations were not central to the decision making processes for national funding calls with the agrifood sector accounting for only 4% of the reach activity ascribed to Exchequer funding. Nevertheless funding to the wider nanotechnology area has developed a significant level of expertise and infrastructure capable of upskilling and adaption to help service the agrifood sector and underpin nano-risk assessment activities on the island of Ireland. Future considerations on engagement of the wider nanotechnology community via open communication channels now needs to be addressed to take advantage of the investment.

References
[1] Foresight 2011 The Future of Food and Farming Final Project Report (London: The Government Office for Science).
[2] Hardy A, Benford D et al 2018 ‘EFSA Scientific Committee, Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health’ EFSA Journal; 16(7):5327, 95.
[3] Handford C, Dean M, Spence M, Henchion M, Elliott C and Campbell K, 2014 Nanotechnology in the Agri-Food Industry on the island Of Ireland: applications, opportunities and challenges (Ireland: SafeFood).
[4] Henchion M, McCarthy M, Greehy G, McCarthy S, Dillon E, Williams G and Kavanagh, G 2014 Irish Consumer and Industry Acceptance of Novel Food Technologies: Research Highlights, Implications and Recommendations (Ireland: Teagasc Food Research Centre) p7.
[5] Food Safety Authority of Ireland (FSAI) 2008 The Relevance for Food Safety of Applications of Nanotechnology in the Food and Feed Industries (Dublin: FSAI).
[6] EC 2008 Commission Recommendation of 07/02/2008 on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research Available at: http://ec.europa.eu/research/sciencesociety/document_library/pdf_06/nanocoderecommendai
EFSA Scientific Committee 2009 Scientific Opinion on the potential risks arising from nanoscience and nanotechnologies on food and feed safety EFSA Journal 2009;7(3):958, pp 39 Available at: https://doi.org/10.2903/j.efsa.2009.958 [accessed 30/0/2020].

FP7 NANOIMPACTNET Available at: https://cordis.europa.eu/project/id/218539 [accessed 30/10/2020].

Nanofind Available at: http://www.nanofind.eu/ [accessed 30/0/2020].

European Parliament and Council 2015 Regulation (EU) 2015/2283 of the European Parliament and of the council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 Off J Eur Union L 327 pp 1-22.

European Commission 2015 Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food Off J Eur Union L328 pp 20-29.

European Parliament and Council 2011b Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers Off J Eur Union L 304 pp18-63.

European Parliament and Council 2008 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives Off J Eur Union L354 pp16-33.

European Parliament and Council 2006 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/105/EC and 2000/21/EC Off J Eur Union L396 (1) pp1-849.

European Union Observatory for nanomaterials (EUON) Completed And Planned REACH Substance Evaluations On Nanomaterials Available at: <https://euon.echa.europa.eu/completed-and-planned-reach-substance-evaluations-on-nanomaterials> [accessed 21 October 2020].

Younes et al 2019 Scientific opinion on the proposed amendment of the EU specifications for titanium dioxide (E 171) with respect to the inclusion of additional parameters related to its particle size distribution EFS Journal, vol 17 issue 7.

Gibson J, Tekiner F, Halfpenny P, Nazroo J, Fagan C, Procter R and Lin, Y 2007 Data mining for social scientists Available at: <https://www.researchgate.net/publication/22878303_Data_mining_for_social_scientists> [accessed 30 October 2020].

Baral U, 2017 ‘Research Data’ in Social Science Methods. Journal of Political Science [online] 17 pp.82-104 Available at: <DOI: https://doi.org/10.3126/jps.v17i0.20515> [accessed 31 October 2020].

Department of Business, Enterprise and Innovation (DBEI) 2018 The Research And Development Budget (R&D) 2017-2018 (Government of Ireland: DBEI).

Research Priority Areas 2018 to 2023 Innovation and Investment Division Department of Business, Enterprise and Innovation Available at: https://dbei.gov.ie/en/Publications [accessed 30/10/2020].

Central Statistics Office (CSO) 2019 Business Expenditure On Research And Development By Nationality Of Ownership, Type Of Funding And Year - Statbank / BERD Nationality Of Ownership / BSA10 (Government of Ireland: CSO).

Department of Business, Enterprise and Innovation (DBEI) 2015 Innovation 2020 (Government ...
[23] Knowledge Transfer Ireland (KTI) 2019 Mission (Government of Ireland: Enterprise Ireland/KTI website).

[24] Draft proposal for a European Partnership under Horizon Europe Partnership for the Assessment of Risk from Chemicals (PARC) 2020 Available at: https://ec.europa.eu/info/sites/info/files/research_and_innovation/funding/documents/ee_rtd_he-partnerships-chemical-risk-assessment.pdf [accessed 30/10/2020].