Who are the UK FSA and the COT? -NAMS Roadmap (2023)

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The <u>UK FSA</u> is an independent Government department working across England, Wales, and Northern Ireland to protect public dietary health and consumers' wider interests in food. The FSA uses expertise and influence so that people can trust that the food they consume is safe and is what it says it is. The Science, Evidence and Research Division (SERD) of the FSA provides strategic analysis, insight, and evidence across the FSA's remit to underpin the development of policies, guidance, and advice on food safety.

The <u>COT</u> assesses chemicals for their potential to harm human health. Scientific evaluations are carried out at the request of the FSA, Department of Health and Social Care (DHSC), UK Health Security Agency (UKHSA), and other government departments and regulatory authorities.

Why are the FSA and COT taking a lead on this?

The FSA responds to food incidents and it is imperative that risk assessments on the safety of a chemical are provided. The data used can only be what is available and sometimes there is very little, or no, toxicological information for a given chemical.

For these chemicals, the use of NAMs will provide a more indicative level of risk and therefore greater confidence in risk assessments that individual compounds can be assessed. This will be fundamental in risk assessment scenarios where limited to no information is available on the toxicity of a chemical.

The FSA and COT have been reviewing the use of NAMs to scope what methods are out there, in order for the best methodologies to be used in risk assessment and understand how these can be incorporated in a regulatory context (<u>Environmental</u>, health and safety alternative testing strategies: Development of <u>methods for potency estimation TOX/2019/70</u>). There is a need for integration of several methodologies which will form part of the integrated approaches to testing and assessment (IATAs). In order to build confidence in what we are trying to achieve this roadmap will not only require the historic 3Rs approach (i.e. replacement, reduction and refinement of animal experiments) but also the expansion to the 6Rs principle: (to also include) reproducibility, relevance, and regulatory acceptance. Furthermore, data capability expansion will need to be taken into consideration.

FSA Digital Vision

In the FSA Chief Scientist Data Science Report (2017), it stated that "Big data and data science bring relatively new tools and techniques to Government analytics".

In the <u>Science Council Working Group on Data Usage and Digital Technology Final</u> <u>Report</u> to the FSA it stated in one of the recommendations: "Encourage the development of data capabilities and skills across the FSA staff base therefore, we want to embrace the new technologies and enhance capabilities for our staff."

Food Security is a top priority: The Government Food Strategy X FSA Strategy = Food is safe + Food you can trust

In the <u>Government food strategy</u> food security is one of the main pillars and using NAMs will enable regulators to make sure food is safe, which underpins the <u>FSA</u> <u>strategy</u> in which the fundamental mission is: food you can trust.

Regulatory Acceptance of NAMs

NAMs and IATAs are currently rarely accepted by regulatory bodies. However, it is clear that we are now at a pivotal point where integration of such (methods/techniques) will be fundamental in more efficient, ethical and rapid risk assessment. The key question is how these approaches can be facilitated in a regulatory setting using the supporting technologies available. The use of these methods, through various case studies, as a 'proof of principle' concept is becoming apparent.