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## Post-market monitoring: why? What? How?

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### 1. Introduction



Food manufacturers have a fundamental responsibility to guarantee the safety of their products prior to resale. Novel food items, food ingredients and genetically modified (GM) crops must pass detailed pre-market risk assessment checks prior to market release to provide assurances that, given particular conditions of exposure, they do not pose any risk for human health, animal health or the environment. Because of their history of safe use, traditional food items serve as the baseline for comparisons of safety for novel or GM foods within the principle of substantial equivalence.

The government has a duty to protect public health, and reports of ill health associated with intakes of any foodstuff are acted on without delay. In the case of novel and GM foods and food ingredients, potential safety hazards must be considered because they have either never before been used as a food, result from a process that has not previously been used for food or have been modified by genetic manipulation. New legislative recommendations are consequently being established to help ensure that such products are also monitored post-market to ensure anticipated consumption levels are accurate, and that they are not associated with unexpected side effects (Regulation (EC) No 1829/2003 22 September 2003).

### 2. Why is post-market monitoring necessary?

The UK Food Standards Agency 'Consumer views of GM food' report (Food Standards Agency 2003) testified that despite recognition among consumers that GM foods have been consumed outside the EU for a number of years without suggestion of associated health problems, concerns regarding the potential long-term health effects of eating GM food remain. Failures by government officials to learn from cases such as the *Escherichia coli* (*E. coli*) O157 outbreak in Central Scotland and BSE in cattle have amplified distrust of science and government, and as a result, consumers have made increased demands for scientific certainty. To endorse findings from pre-market risk assessment checks, assurances for consumer safety are sought via post-market monitoring. The objectives of such are to:

- Ensure that no health issues are associated with over consumption of specific ingredients
- Determine what risks are apparent if intakes of novel foods interact with other nutrients and/or drugs
- Establish longer term effects associated with recommended and observed intake levels
- Assess risks associated with consumption in specific population groups (e.g. pregnant women, children)

### 3. What should post-market monitoring address?

Pre-market risk assessment checks are insufficiently complex to determine exactly who will consume marketed products, how much of a product will be consumed post-release, and whether unpredicted side effects will result among 'at risk' population groups such as children, pregnant women or allergic individuals or after prolonged exposure. This has resulted in three questions of particular interest to scientists considering post-market monitoring (Wal *et al.* 2003):

### 3.1 Is the product use as predicted/recommended?

Assessing dietary intake using any method is subject to uncertainties. Collection of sales or purchase data, for example, may provide only data on foods purchased for consumption within the home, while reliance on participants' memories for dietary diary or recall data leaves such collection methods open to misreporting biases (Robertson *et al.* 2004). Where intakes of novel food items with altered nutritional composition, nutritional value or specific health claims are of interest, consumption levels may be elevated above that estimated using a traditional counterpart and compositional information may be less accessible than that for traditional products. Assessing intakes of composite food items will be easier than tracing ingredients contained within a number of different products in differing concentrations, however data collection will remain open to potential misreporting biases. It is essential that precise intake data is collected to confirm absence of adverse side effects at true consumer exposure levels, and that dietary assessment data is sufficiently detailed to enable an assessment of food, nutrient and drug interaction effects to be made.

### 3.2 Are the known side effects as predicted?

The utility of post-market monitoring is not to confirm the beneficial effects under which claims novel foods are marketed, but to quantify true exposure levels and observe any adverse effects highlighted in the pre-market risk assessment checks to ensure they do not have any significant impact on health outcomes. This requires that any post-market monitoring campaign assesses novel food items on a case-by-case basis, addressing possible side effects noted in the pre-market risk assessment.

### 3.3 Does the product cause unexpected side effects?

Without regulated post-market monitoring of novel food intakes, unintended side effects are generally observed by food manufacturers using a passive signalling system detailing consumer complaints reported via consumer care lines. This method is potentially biased as it requires the consumer to attribute their symptoms to a certain product. As 'unintended' side effects could include any number of health outcomes (e.g. gastric, allergenic or chronic outcomes such as cancer), post-market monitoring campaigns must be all encompassing. To address the financial restrictions imposed by such a system, novel foods requiring post-market monitoring must be assessed on a case-by-case basis, and the scope of the methodology influenced by the findings of the pre-market safety checks.

## 4. How should post-market monitoring be completed?



There do not appear to be any specific systems in place across the world to monitor long term intakes of novel food items post-market and concerns exist surrounding the real feasibility of conducting post-market monitoring. The UK Food Standards Agency has commissioned one of the only feasibility studies to be completed so far (Elliott *et al.* 2003; Robertson *et al.* 2004). This project used ten years of commercially available food purchase data, and traced household composition, regional and temporal disparities in purchase patterns for 4 groups of 'marker foods'. This research group highlighted extensive modifications necessary to the database before it could feasibly be used for post-market surveillance; for example, additional information on foods consumed outside the home, and a direct linkage system between product barcodes and ingredient/nutrient composition information would be required. This project did not attempt to link food purchase data with health data, and ultimately concluded that surveillance of food intakes must be prospective to enable eventual linkage with putative health effects (Elliott *et al.* 2003).

In Australia, the Australia New Zealand Food Authority (ANZFA) has described their use of a dietary modelling system to predict consumption of complete novel foods or chemicals within such products. This relies on the pre-market risk assessment estimate of intake (i.e. that all equivalent 'traditional' foods

are replaced with the novel food) being true. This system combines estimated exposure data (collated from available food consumption and nutrient, additive, contaminant and agricultural chemical residue concentration data) and reference health standards data where available, for the complete population and specific population subgroups. However, it has not yet been used to complete post-market monitoring of novel foods, therefore, its true feasibility is not yet certain (Organization for Economic Co-operation and Development 2003).

## 5. Looking ahead

Although the necessity for post-market monitoring of novel and GM foods and food ingredients is well justified, guidance does not go far enough in terms of practical advice. Consumer groups are seldom accurately definable, traceability from raw ingredients to finished products is not straightforward, and the causal chain from ingestion of foods and/or ingredients to health effects is not clear cut. Post-market monitoring must address issues of importance to manufacturers, consumers, health professionals and the government. The ideal methodology under which to conduct post-market monitoring is not yet known.

Post-market monitoring efforts are underway to establish who is consuming phytosterol ester-containing spreads, thus determining whether these are reaching the target consumer group or are being consumed by non-target consumers (Organization for Economic Co-operation and Development 2003). Although this cannot be considered long-term monitoring and although it is unlikely to capture all relevant health outcome data, this work is an important first step. Scientists await the results of this work optimistically, encouraged that they will inform the increasingly complex and problematic research question "How best should we conduct post-market monitoring?"

## 6. References

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### About the author

Claire Robertson is a Senior Lecturer in the School of Biosciences, University of Westminster. A registered nutritionist, Claire has a BSc (hons) in Applied Human Nutrition from Queen Margaret University College, Edinburgh, and Ph.D. in Nutritional Epidemiology from the Queens University of Belfast where she was a site coordinator and nutritionist for the INTERMAP study. Claire coordinated a UK Food Standards Agency project at Imperial College, London investigating the feasibility of conducting post-market surveillance of novel foods using market-research data. She is currently actively involved in an expert group on Post-Market Monitoring co-ordinated by Paul Hepburn (Unilever) at the International Life Sciences Institute in Brussels (<http://europe.ilsa.org>). Claire has published in several international journals, and given presentations to national and international conferences and to stakeholder groups.