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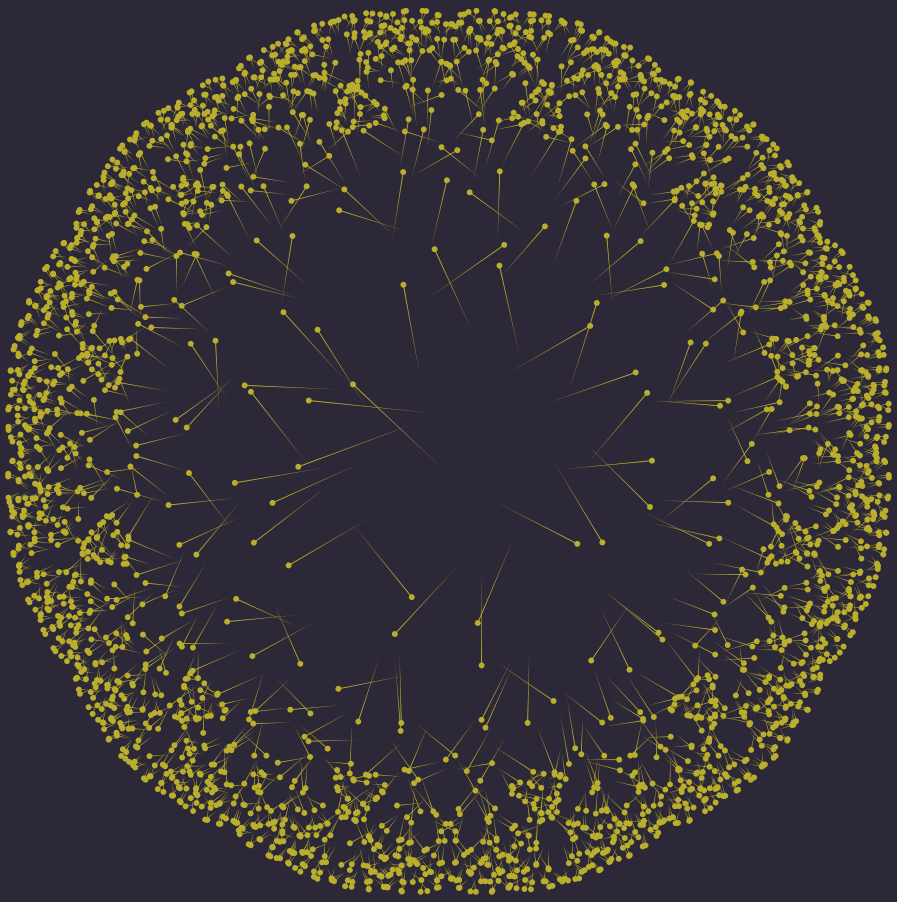
Original thinking... applied



fapas

PUTTING THE 'QUALITY' INTO EXTERNAL **QUALITY CONTROL**

Applying External Quality Control in Food Testing Laboratories – Burden or Essential?

Quality control (QC) in food testing laboratories is often thought of as an essential burden. A lot of time and effort (and money) is put into establishing QC mechanisms, especially for accreditation purposes. In fact quality control should be built into your everyday routine and have minimal adverse impact on the business, it is essential to building a successful business that delivers products that meet or exceed customers' expectations. It also forms the basis of an efficient business that minimises waste and operates at high levels of productivity. So careful consideration should be given to the adverse effect on the business of neglecting QC.

Product recalls impact both financially and reputationally and in many cases could be avoided by using effective QC tools. For laboratories, one of those QC tools should be an external reference, that is one that the laboratory has no direct control over. Such tools include proficiency testing (PT) and use of reference materials (RM) from an external supplier. In this paper we look to evaluate these external tools and how they can be applied in routine laboratory QC procedures. We also look at how their results should be interpreted and the benefits to the food testing sector.

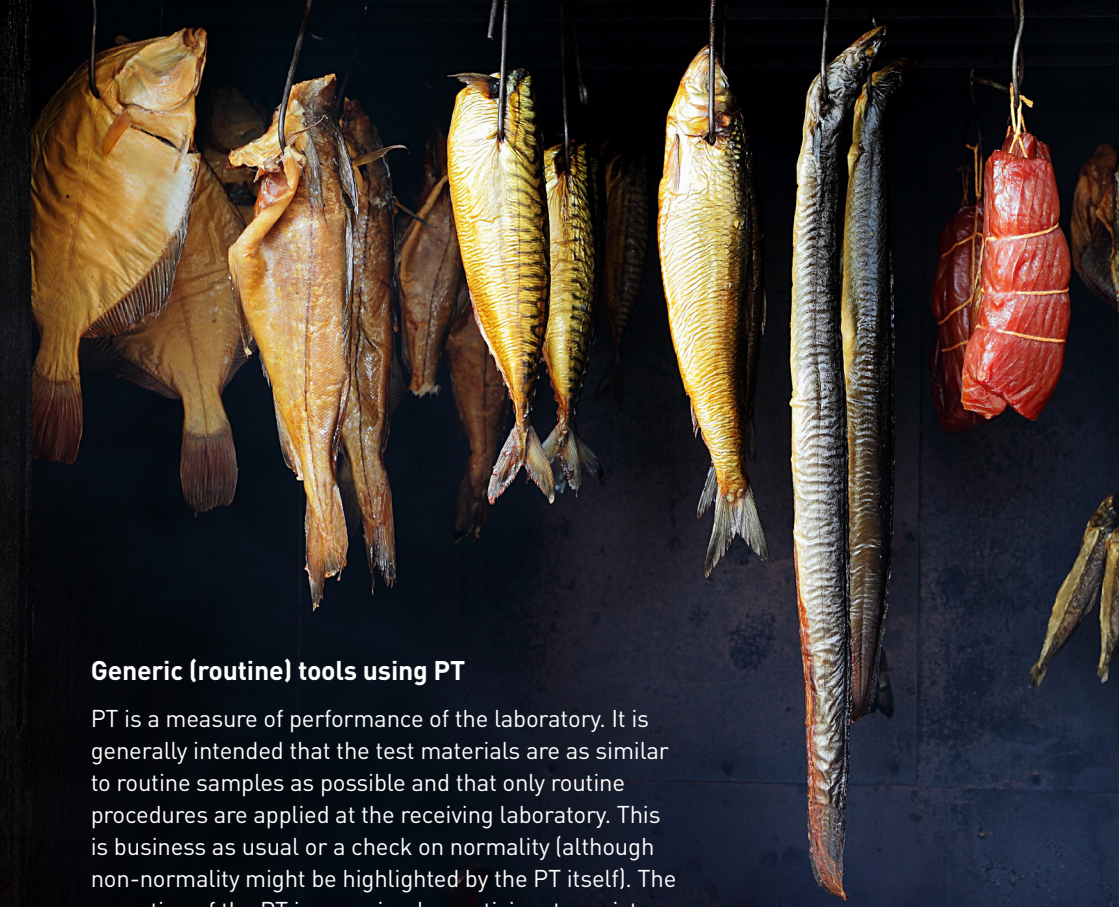
Recent research from Lockton reveals 38% of manufacturers surveyed claim safety standards are being eroded as a direct result of cost cutting, while a further 32% agree production facilities are less safe than in the past due to pressure to cut costs.

What is the purpose of QC?

Any laboratory process should have some quality control checks in place. Increasingly, this is formalised via accreditation to a recognised international standard, typically ISO 17025. Legislators might make this a requirement, usually mandatory for official control laboratories, which has been the case in the EU for many years now. In the US, the Food Safery Modernisation Act is also mandating compliance to international standards. It is widely acknowledged that the best mechanism for demonstrating competence is via the use of an external quality control, i.e. one that is generated outside the laboratory. Usually this is interpreted to mean taking part in a PT scheme, provided by a professional PT provider. Compliance to international standards of testing is best supported by a PT provider with a wide international reach.

We often come across the term 'fit-for-purpose' in relation to QC. The first question to ask is, what is the purpose? There might be several different answers, all of which require a different type of QC, such as:

- **Is the analysis routine?**
- **Is the QC for the entire laboratory process or for individual parameters?**
- **Is it only for today or something to repeat next month?**
- **Who will ask for the QC data? If there are multiple stakeholders, do they want the same QC measure or different measures?**



Generic (routine) tools using PT

PT is a measure of performance of the laboratory. It is generally intended that the test materials are as similar to routine samples as possible and that only routine procedures are applied at the receiving laboratory. This is business as usual or a check on normality (although non-normality might be highlighted by the PT itself). The operation of the PT is very simple: participants register, test samples are received and analysed at the laboratories, results are returned and a report issued.

The statistical analysis and performance assessments are entirely in the hands of the PT provider and the participants receive their z-score[1] (or other assessment). There is no attribution to an individual or (usually) method parameter, the statistics are robust due to a large dataset and objective criteria. The PT results can be used to support accreditation but it is only a single instance of QC. Long term trends must be built up over many more similar PTs, possibly over a period of several years.

1 z-Scores were devised to provide a transparent but widely-applicable scoring system for participants in proficiency tests for analytical laboratories

Real life supply chain challenges with meat products and how PT can highlight adulteration

In the food industry, there have been various press headlines highlighting many issues of deliberate adulteration as well as contamination. Adulteration occurs for many reasons, the main one being economic gain, that is to say diluting a product with an undeclared cheaper ingredient. Adulteration therefore tends to be at levels sufficient enough to deliver an economic gain, typically at concentration levels of several percent. This is enough to deliver the exercise financially worthwhile but not quite enough to make the consumer suspicious. The obvious example is the horse meat scandal. Contamination on the other hand is due to poor handling practices of ingredients, with contamination levels at sub-percent concentrations. This is particularly important for the control of allergenic ingredients in food production, for example, or the transfer of veterinary medicines from a dosing feedstock to a general feed. There is also the question of authenticity or provenance of a product, such as basmati rice, olive oil or beef with defined country of origin.

For the meat industry, there is the possibility to produce proficiency tests for both the adulteration and contamination scenarios, despite the large difference in concentration levels. The difficulty is in the production of the test material. A good PT material must be appropriate for its purpose, to resemble as closely as possible the kind of sample that the laboratory would ordinarily receive in its routine work. The test material must also be equivalent for each participant (and there might typically be up to 100 laboratories taking part in any one PT). Hence, the test material will be a homogenised item and the PT provider has to ensure that each item is the same as all the others. For the adulteration scenario, producing a beef mince material containing about 5% of horse meat presents little difficulty for an experienced PT provider.

The contamination scenario is very different. Meat is a very heterogeneous material containing different structures of proteins, fats and membranes even in a lean cut of meat. In order to contaminate a beef mince material with sub-percent levels of pork and make it homogeneous presents a unique challenge but one that Fapas® has overcome.

Meat Adulteration and Contamination PT in Practice

Both types of PT are qualitative PTs in which the base matrix is known to participants (e.g. beef). Participants return results of 'detected' or 'not detected' for the added species of interest. In the case of the adulteration PT, a list of potential added species is provided (e.g. lamb, pork, chicken, horse) and the base matrix will have one or more of these potential species added to it, typically between 2 and 5% w/w. Participants can also state which other species they analyse for that are not on the potential list (e.g. ostrich or goat). The correct detection of a known adulterant is assessed as 'satisfactory' performance, supported by the consensus of all participants' responses. Failure to detect a known adulterant is assessed as 'not satisfactory' performance, again supported by the consensus of all participants' responses. Detection of a species that was not deliberately added to the base matrix (false positive) is compared to the consensus of all participants' responses and assessed as 'disagrees'. This allows for possible cross-contamination of the base matrix at its retail (uncontrolled) source.

Outcome of the PTs

Analyte	Assignment	Consensus Results	Total Results	Results Agreeing with Assignment %
Chicken	Present	61	61	100
Horse	Absent	58	58	100
Lamb	Present	48	50	96
Pork	Present	64	66	97

Table 1, summary results for Fapas® PT 2971 (Product Code FCAA4-MRP2). The assignment is the known preparation of the material.

Two examples are provided here, one each of the two types of PT. The summary results for the adulteration Fapas® PT 2971 (Product Code FCAA4-MRP2 Beef Authenticity) are provided in Table 1. The base matrix was beef to which was added chicken, lamb and pork but not horse. Results were returned by 67 laboratories within the timeframe of the PT (a few weeks).

Summary of the outcome of the PTs

All the laboratories that submitted results for chicken and horse detections agreed that chicken was present and horse was absent. This also agrees with the known preparation of the material. However, two laboratories failed to detect the presence of lamb or pork. Many participants additionally submitted confirmation that beef was present in the base matrix and there was also a range of other species that were included in participants' screens. These included goat, turkey, dog, deer, fish and duck. A majority of participants used DNA methods, either PCR or DNA testing kits. Non-DNA methods used by participants were ELISA kits of various manufacturers.

Specific Tools using RM (Reference Materials)

With many PTs, there is an excess of materials produced. These have uses beyond the PT as quality control samples or reference materials. This benefits participants who need to investigate their unsatisfactory performance in a PT. However there are also benefits for ongoing quality control trending purposes, staff training or method validation exercises. The materials are characterised by the PT exercise itself and so provide a very high degree of confidence in the 'correct' result.

RMs & QCs are available see fapas.com for details

Summary

As we all know the provenance of food, especially meat products, is a sensitive topic thankfully in addition to proficiency testing there are tools available to support producers in demonstrating compliance with legislators and other authorities.

One such tool is reviewing emerging issues and increasing risks in the supply chain by using HorizonScan, a database of global raw material and commodity issues covering all areas of food integrity. Recent results provided by HorizonScan showed that fraudulent activity still features heavily across all meats and meat products.

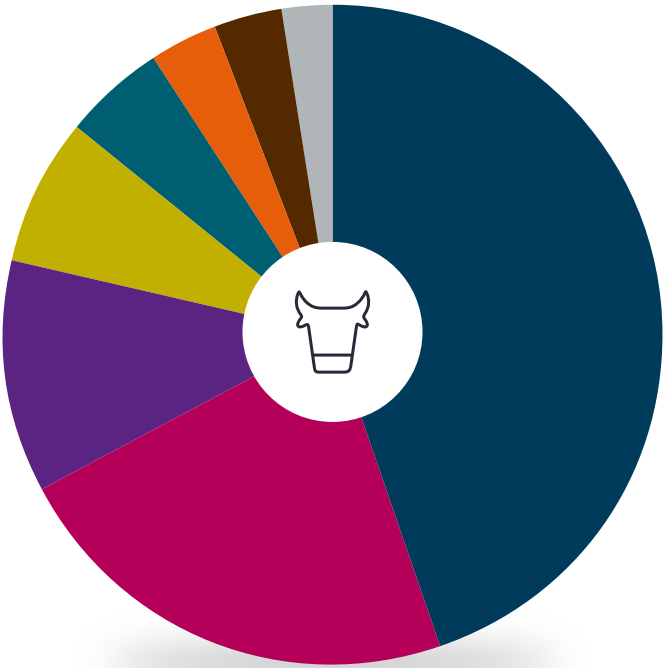
Number of Issues Being Reported

Food Group	Change this year vs last year (%)	Now (2017)	Then (2016)
Fruit and Vegetables	Down by 20.5%	1720	2163
Nuts, Nut Products and Seeds	Up by 5.8%	511	483
Herbs and Spices	Down by 17.6%	709	860
Seafood	Up by 9.9%	1603	1458
Dairy	Up by 2.7%	455	443
Meat and Meat Products (other than poultry)	**Up by 25.6%**	**716**	**570**
Poultry Meat and Poultry Products	Down by 0.8%	262	264

Meat Products – up 26% in number of issues being report – highest across any food group

Meat and meat products

(other than poultry)



Total of 716 issues

Key	Commodity	%	Main issues
	Meat Products and Meat Preparations	39.90%	Listeria, foreign bodies, fraudulent documentation, Salmonella or E.coli
	Meat Products – Sausages	20.10%	Salmonella, fraudulent documentation or Listeria
	Meat – Bovine (Beef, Veal, Cow)	10.20%	E.coli
	Meat Products – Pork Hams	6.60%	Altered organolepsis, Listeria or fraudulent documentation
	Meat – Porcine	4.30%	Salmonella, veterinary drugs or E.coli
	Meat, Minced, Ground – Bovin	3.10%	E.coli or foreign bodies
	Meat – Other, Mixed or Unspecified	2.90%	E.coli, unapproved premises or Salmonella
	Offal – Mixed or Unspecified	2.10%	Altered organolepsis, Listeria, undeclared allergens, insufficient controls or mislabelling

Evaluating the Science Behind PT and Putting this into Practice

What PT can deliver for your business

Safety and quality information on foods and other products, based on data supplied by analytical laboratories, is very important to all involved in the food chain. A lack of an independent assessment of the quality of analytical data would hamper the work of enforcement authorities as well as limit the scope and reliability of surveillance work. With increasing demands for independent proof of competence from regulatory bodies and food businesses, proficiency testing is pivotal to all laboratories testing samples for quality and safety in every country. PT is an independent and unbiased assessment of all aspects of a laboratory's performance, both human and hardware, and is used to evidence accuracy, sensitivity, reproducibility and reliability of analytical data.

Quality programmes are usually established by national regulations, to obtain impartial evidence to evaluate performance of a service provider. PT is one of three essential elements ensuring laboratory quality assurance. This, together with laboratory accreditation, which demonstrate compliance with the requirements of BS/EN/ISO/IEC 17025[1], and the use of validated methods, which conform to "The Protocol for the Design, Conduct and Interpretation of Collaborative Studies", assists demonstrate their competence and the quality of analytical data they produce.

1 General requirements for the competence of testing and calibration

PT is underpinned by Research & Development

The Ministry of Agriculture, Fisheries and Food (MAFF) as a result of inconsistencies in data from laboratories testing for food contamination and public health concerns created an advisory panel, formed from senior experts in the UK food analysis community to develop a testing model that would provide consistent results. The advisory panel, which was subsequently enlarged to include EU and food analyst representatives, decided on a statistical methodology' to be used in PT assessments that all laboratories would be measured against. To this day the advisory panel remains the main governing advisory body for Fera's PT business Fera's PT customers[2].

Fera's proficiency testing was quickly identified as a very popular scheme for speedy, accurate and fair assessment of analytical performances and a self-help tool for UK laboratories to improve their analytical practices. Indeed other countries, which did not have a scheme of their own also adopted Fera's PT to improve their analytical practices. Over the years, Fera's PT scheme has grown (Figure 1) and expanded globally so much so that it now offers over 400 individual tests within four schemes in the fields of food chemistry, microbiology, GMO, and water and environment analyses, as well as, bespoke schemes.

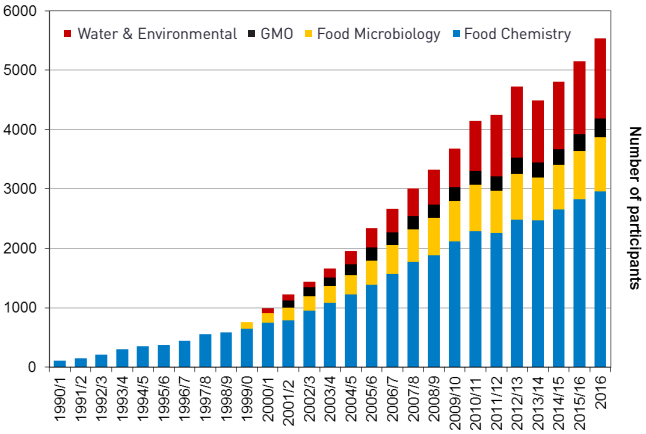


Figure 1. PT schemes' growth – number of participants per annum

2 Here and thereafter Fera refers to Fera Science Ltd and all its predecessor, i.e. the Food and Environent Research Agency, Central Science Laboratory and MAFF

PT materials are sourced from external organisations, to ensure their homogeneity, stability and suitability in terms of a matrix composition, concentration range, level of analyte, etc.

An introduction and/or revision of PT rounds and schemes is often driven by new or changed regulations.

An example of this is pesticide residues where it was shown in a PT that values of the spiking level is systematically higher than the assigned value, which was explained by the nature of extraction procedures, showing that the analytical methods involving more rigorous extractions recover more pesticides from food matrices. However, such methods are costly to execute and not really fit for the purpose in routine analyses. Given these limitations, it was concluded that the assigned value is more appropriate for consensuses in Fapas round.

Source: Fera Science Ltd, Science Impact Case Study - **Proficiency Testing (PT) in Action (Dec 2017)**

The Vital Tool in Your Testing Armoury

PT is a key part of food testing services, which helps to ensure the safety and quality of the food chain. The global market for food testing services is projected to grow from $13Bn in 2017 to $19Bn[3] in five years. The growth is driven by increasing focus on food quality, stringent food safety regulations, advances in food testing technologies and commercial availability of rapid screening tests. Europe represents the largest food testing market worldwide prompted by increasing consumer awareness over healthy food options, improvements in industrial hygiene standards in food processing, efforts of regulatory bodies to ensure safety and authenticity of food products. Asia-Pacific ranks as the fastest growing market, with the compound annual growth rate of 8.5% in the next five years, led by growing population, escalating demands for food, strong empathies on food security and safety in emerging markets such as China and India. Rapid growth in food trade in developing nations and the need to comply with the quality standards are also driving demands for food testing services.

3 http://www.strategyr.com/Marketresearch/Food_Safety_Testing Market_Trends.asp

Conclusion

The confidence in analytical data provided to producers can be enhanced through using proficiency testing. Proficiency testing provides clear evidence from an independent source that the laboratory supplying the analytical service is competent. PT exercises, such as those run by Fera Science Limited PT scheme Fapas®, exist to support the detection of both adulteration and contamination of meat products for purposes of unscrupulous economic gain or incorrect compliance.

Each year, Fera issues thousands of Fapas Proficiency Test certificates and produces hundreds of PT reports, which participants use to determine their laboratory practices to improve the quality of analytical data. PT reports capture detailed statistical method information to identify trends in analyses, which can lead to standards being withdrawn. An example of which is the withdrawal of standards when PT results highlighted the influence of stereoisomers in chloramphenical reference standards to confirming the hypothesis of incomplete digestion of riboflavin-5-phosphate of vitamin B2 in liquid dietary supplements.

Fera Science Limited proficiency testing division Fapas has published 31 papers in the last 18 years, which have been cited 330 times and prompted changes in PT schemes and analytical practices in some laboratories.

Fera Science Ltd, Science Impact Case Study - **Proficiency Testing (PT) in Action (Dec 2017)**

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