



FAPAS - Proficiency Testing Overview and Protocol

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Introduction to Fera

Feraについて

The Food and Environment Research Agency

Vested on 1st April 2009

Central Science Laboratory, Plant Health Division, Plant
Variety Rights Office and Seeds Division, Government
Decontamination Service

Executive agency of Defra, Department for
Environment, Food and Rural Affairs, UK

www.defra.gov.uk/fera



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Research Agency



Latest issues 最近の課題

- Food safety issues - concern for customers, nation and whole world
食の安全性の問題 – 顧客・国・世界レベルでの懸念事項
- Proof of competence from regulatory bodies and customers
監督官庁や顧客から分析技能の証明要求
- Laboratory
ラボへの要求事項
 - Need to be able to perform test properly
分析が正しく行われているか
 - Meet international standard
国際基準への適合

What is Proficiency Testing? 技能試験とは

The ISO definition of laboratory proficiency testing is:

技能試験のISO定義:

“ Determination of laboratory testing performance by means of inter laboratory comparisons”

“（技能試験とは、）複数の試験所間比較によって、ラボの分析技能を決定することである。”

PT is a test of *accuracy* by comparing the laboratory results with the ‘true’ value

技能試験とは、得られた分析結果を‘真’の値と比較することにより、「分析技能の確かさ」を試験することである。

What is proficiency testing?

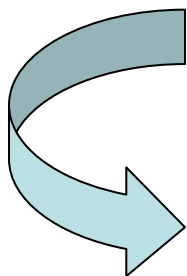
技能試験とは?



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If I ask you to do an analysis, how do I know
you're giving me the right answer?

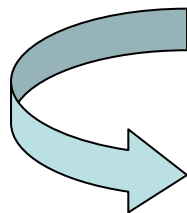
分析技能証明を求められた場合の適切な回答は?



Validated method? 有効な分析法?

Internal QC? 内部制度管理?

Accreditation? (ISO 17025) ISO 17025認定?



Fit-for-purpose

Bias against external
reference

第三者による評価

What is FAPAS?

FAPASとは?

- A **Proficiency Testing (PT) Provider**, running 5 food and environment PT schemes
5つの食品・環境分野技能試験スキームを実施する技能試験プロバイダである
- FAPAS operates from Fera with support from the parent organisation
FeraとUK政府との連携によりFAPASは運営されている
- Participants receive a **confidential** and accredited service of the highest scientific quality
参加者は、匿名で公認の最高品質のサービスを受けられます。

FAPAS – its history

- **FAPAS:** established 1990 by MAFF at their Food Science Laboratory in Norwich, due to concern over UK analytical standards
FAPASは1990年にUKの食品分析標準に対する懸念からの、農漁食糧省Food Science Laboratoryにより設立された。
- **Quality Assessment Scheme (QAS)** commissioned in 1993 by MAFF to test their UK food surveillance micro labs – **FEPAS** launched 1997
食品微生物試験を行うUKラボを試験するために1993年に品質管理スキームが組織され、1997年にFEPASが開始。
- **LEAP:** set up in 1970s by Yorkshire Water, externalised 1994 and taken over by CSL in 2000
LEAPは1970年代にYorkshire Waterによって開始。1994年に第三者へ移管され、CSLに引き継がれた。
- **GMO Scheme** launched by CSL in April 2001 and later branded as **GeMMA**
遺伝子組換え食品スキームは2001年4月にCSLによって開始され、後にGeMMAになった。
- **Plant Health Scheme (PhytoPAS)** launched by CSL in 2005
植物防疫スキームは2005年にCSLで開始された。

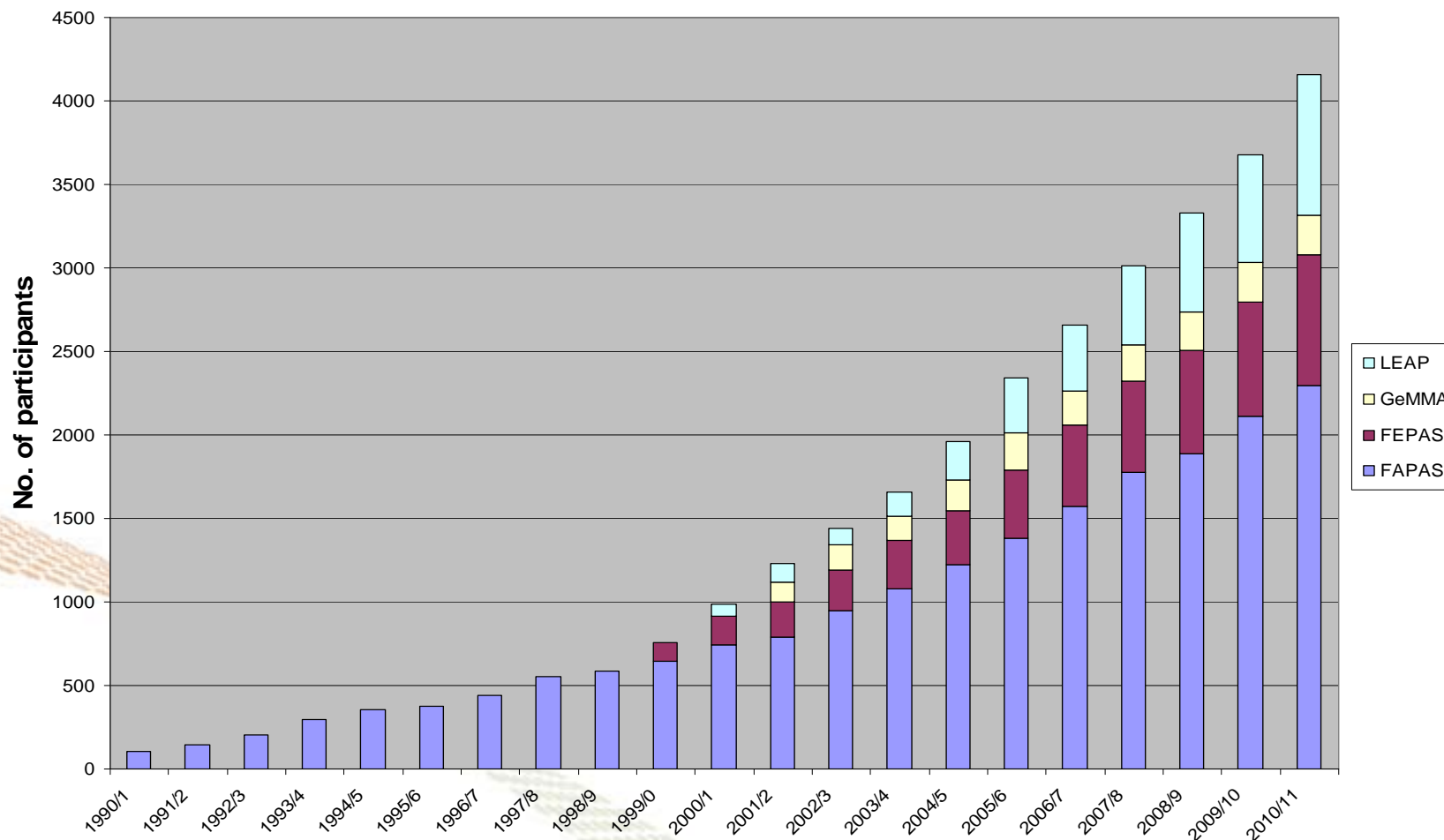
Scheme growth 1990-2011

参加者数の推移



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Scheme growth - number of participants per scheme per annum



FAPAS – global spread 2010

2010年度の世界的な広がり

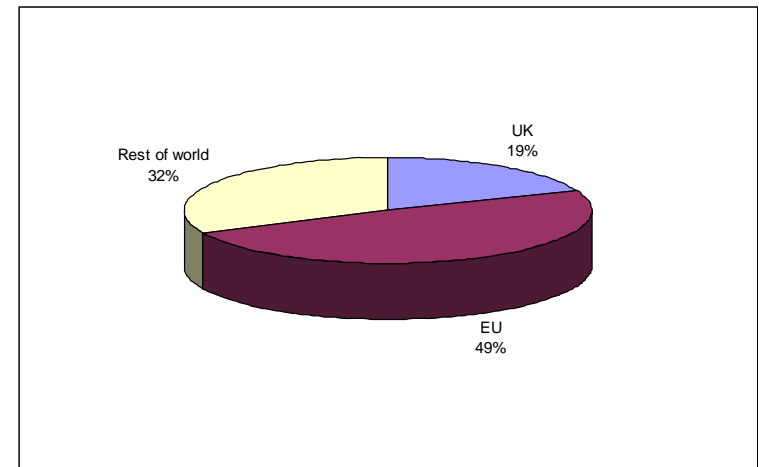
- More than 30 agents in 27 countries

世界27カ国で30社以上の代理店

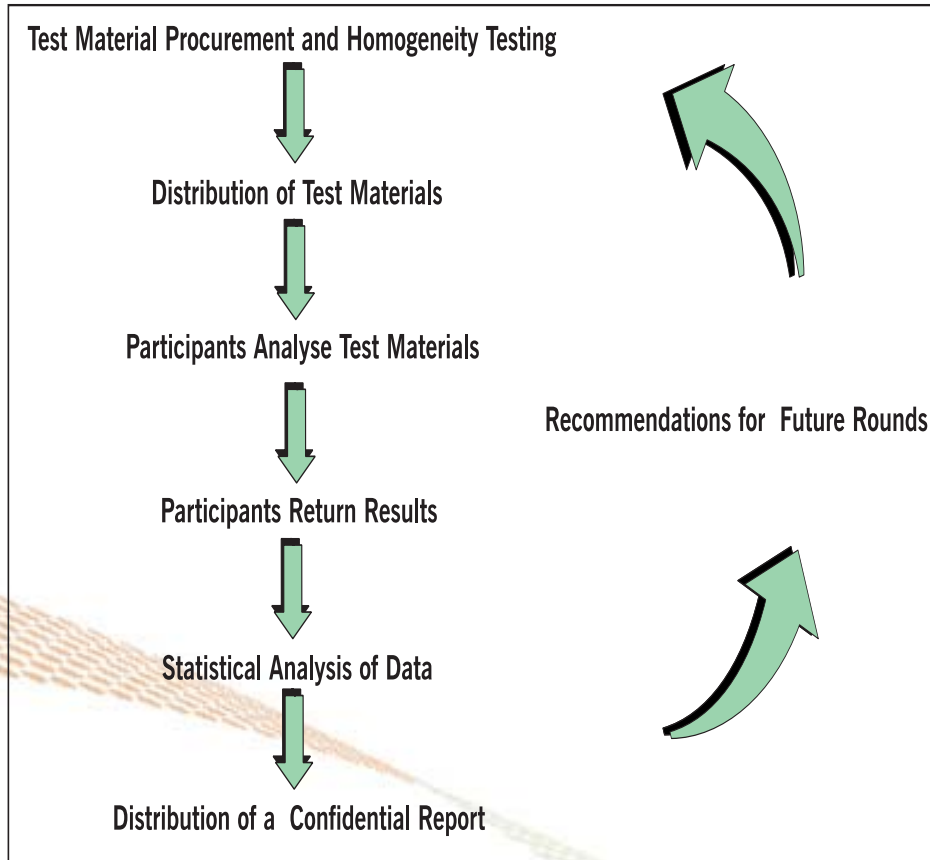
- More than 4000 laboratories registered in over 100 countries, distributed:

世界100カ国以上で4000以上のラボが登録

- UK 19%
- EU 49%
- Rest of world 32%



FAPAS –the PT process



- Prepare test material (試料調製)
- Check the test material is homogenous (均質性試験)
- Distribute test material (試料配布)
- Receive participants results (結果報告)
- Statistically assess participants results (統計処理)
- Produce the PT report (レポート作成)
- Distribute the report to all participants (レポート発行)
- Whole process informs future PTs (次回の技能試験への反映)

International Harmonised Protocol

FAPAS – the people resource

FAPAS-運営スタッフ

- 30 staff, including scientists, admin, business development, sales, dispatch and IT support (we are all Fera staff)

科学者、管理、事業開発、営業、発送、情報システムスタッフの30名により運営されている。

- Advisory Committees for the major schemes, comprising:

メジャースキーム顧問機関の構成

- UK and EU scientists from industry, trade associations, Public Analysts, RSC/AMC, UK FSA, Environment Agency, DWI, UK government departments, academia

工業、貿易関連、公的機関の分析者、化学会・分析化学委員、UK食品標準局、水道局視察団、UK政府機関、学術機関

Quality – accredited to ISO 9001 and ISO Guide 43 (UKAS)



Transition to ISO 17043

www.fapas.com



FAPAS Proficiency testing schemes - Quality assurance for laboratories worldwide - Mozilla Firefox

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FAPAS

FAPAS is the largest and most comprehensive analytical chemistry proficiency testing scheme in the food sector. The scheme has more than 2000 participants in over 100 countries.

[FAPAS](#) [FEPAS](#) [GeMMA](#) [LEAP](#) [PhytoPAS](#) [Bespoke](#)

Latest news

The British Measurement & Testing Association (BMTA) - 01/03/2011

The British Measurement & Testing Association (BMTA) is the trade and technology association for laboratory-based organisations. The Association has almost 100 member organisations representing about 300 UKAS accredited laboratories. BMTA represents its members' interests to UKAS, BSI and Government Departments. Other membership features include technical events, news and information services, tender opportunities alerting, the opportunity to represent BMTA on BSI committees and free access to reports of the National Measurement System. BMTA also organises and contributes to the UK national membership of EUROLAB and has two places on the UKAS Policy Advisory Forum.

<http://www.bmta.co.uk>

Search

Search our currently available proficiency tests and quality control materials by matrix or analyte/determinand:

Search the product catalogue:

Enter product search [Search](#)

Search our website for details on how we operate, other services and information:

Search the fapas.com website:

Search fapas.com [Search](#)

Important changes to FAPAS ordering processes

From now on we shall now require your orders in advance of the dispatch date. The advance dates are as follows: FAPAS - 14 days before dispatch date, FEPAS - 30 days before dispatch date, GeMMA - 14 days before dispatch date, LEAP - 14 days before dispatch date. At this point the tests will be removed from the website. For prepayment orders please make sure that we have received your payment by...

The test material

試験サンプルについて

Liquid or solid? Oily or aqueous?

液体か固体か? 多脂性か含水性か?

Stable or unstable?

安定性があるか不安定か?

Binding to matrix?

マトリックスへの結合?

Storage / transport / container?

保管/輸送/サンプル/容器?

Incurred (natural) analyte or spiked?

自然汚染物質か添加物質?

Contaminated? (GM)

汚染?(遺伝子組換)



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How do I know that my test material sample is the same as
your test material sample?

技能試験サンプルを実際の分析サンプルと同等のモノとして準備するには?

Homogeneity testing

均一性試験

ALL test materials are heterogeneous

全ての試験サンプルは不均一である

Sufficient homogeneity is the key principle

十分な均一性は技能試験の基本原理である。

Differences between individual test portions will not significantly affect the outcome of the test

個々の試料間の違いは技能試験の結果に影響するほど大きいものであってはならない

Fit for purpose

The assigned value

付与値について

- In most FAPAS PTs, is calculated from the consensus of participants' results

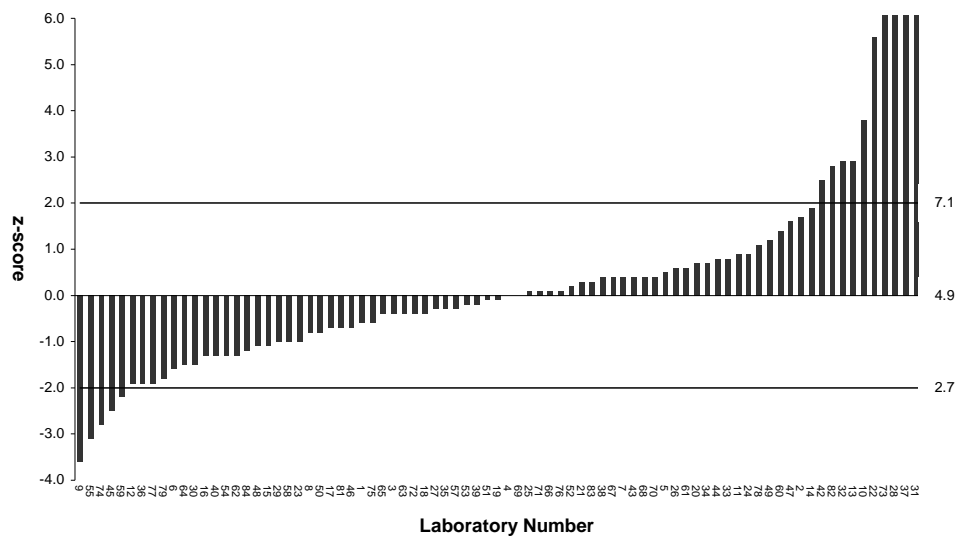
FAPASでは提出された結果のコンセンサスから付与値を導き出されている。

- The best estimate of the true value
最も適した真値の算出
- The real value is unknown
実質添加値は不明である
- From robust mean, median or mode
ロバスト平均から、中央値、最頻値
- Robust mean \neq Arithmetic mean
ロバスト平均 \neq 算術平均値

Example results and z-scores

結果とZスコアの例

laboratory number	analyte		
	assigned value	AFB ₁ 4.97 µg/kg	
	result µg/kg	recovery %	z-score
001	4.28	68.9	-0.6
002	6.78	100	1.7
003	4.5	106	-0.4
004	5.0	86	0.0
005	5.56	88.6	0.5
006	3.2	80	-1.6
007	5.4	95.6	0.4
008	4.07	81.8	-0.8
009	1.0	96	-3.6
010	9.1	63.65	3.8
011	6.0	75	0.9
012	2.9	79.2	-1.9
013	8.20	101.62	2.9
014	7.09	103	1.9
015	3.82	113	-1.1



The z-score

FAPAS-参加者が報告した結果の分析

$$Z = \frac{(x - x_a)}{\sigma_p}$$

where:

x = participant's result 参加者の結果

x_a = the assigned value 付与値

σ_p = standard deviation for proficiency 技能上の標準偏差

z-Score interpretation

Zスコアの解釈

- For a normal distribution, approximately 1 in 20 results will have a z-score outside the limits $|z| > 2$
通常の正規分布では、およそ20回の内1回は $|Z| > 2$ になる可能性がある。
- A z-score outside $|z| > 3$ should have an investigative action
 $|z| > 3$ の場合は改善措置の必要がる。
- *Information only* not evaluative (high uncertainty)
情報としてとらえ、評価には用いない(不確かさが高い)

Test Report



- Confidential : 匿名性

Laboratories given code numbers

各参加ラボにはコードナンバーが与えられる

- Comprehensive : レポートの概要

test material preparation

分析試料の準備について

homogeneity testing and the statistical assessment

均一性試験と統計処理について

participants' results

各参加者の結果

calculation of assigned value

付与値の算出について

standard deviation for proficiency

ターゲット標準偏差について

tables and charts of the results and z-scores

結果とZスコアの表及びチャート

participants' methodology

参加者の用いた分析方法について

Additional services



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- Advice service to participants who perform poorly
技能試験結果が思わしくなかった参加者に対する助言
- z-Score interpretation
Zスコアの解釈について
- Surplus test materials can be sold as 'quality control' samples
(*not certified reference materials*)
内部精度管理としての余剰サンプルの提供
- Training
指導

- Advisory Committee
顧問機関
- Scientific advice and support to FAPAS
科学的助言とFAPASへのサポート

Useful references

- [1] M. Thompson, S. Ellison and R. Wood, The International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories, *Pure Appl. Chem.*, 2006, **78(1)**, 145 –196.
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- [3] Analytical Methods Committee, Robust Statistics – How not to reject outliers Part 1. Basic Concepts, *Analyst*, 1989, **114**, 1693-1697
- [4] ISO 13528:2005, Statistical methods for use in proficiency testing by interlaboratory comparisons, Annex C.
- [5] P.J. Lowthian, and M. Thompson, Bump-hunting for the proficiency tester – searching for multimodality, *Analyst*, 2002, **127**, 1359-1364
- [6] M. Thompson, Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing, *Analyst*, 2000, **125**, 385-386
- [7] M. Thompson, *et al*, 2006, Scoring in GMO Proficiency Tests based on log-transformed results, *J. AOAC Int.*, **89(1)**, 232-239.
- [8] ISO 17043 Conformity Assessment – General requirements for proficiency testing

Thanks to...

Ken Mathieson, Amanda Reynolds

FAPAS colleagues

FAPAS customers

See www.fapas.com



f a p a s

Fin