GMOs in Seed Testing: the ISTA Perspective

Enrico Noli

International Seed Testing Association

GMO Committee

Seed
strategic element for development

- The first step in the food chain
- Seed is the vehicle of genetic innovation
- A steady availability of seed (seed security) is necessary for efficient agricultural production
- High quality seed is an important mean for achieving successful agricultural production

Seed Quality

Physical

- Specific purity
- Absence of weeds
- 1000-Seed Weight
- Moisture

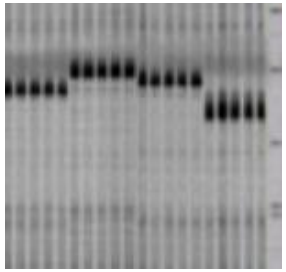
Health

- Absence of Pathogens

Physiological

- Viability
- Germinability
- Vigour

Genetic



- Varietal Identity
- Varietal Purity

GMO presence
Trait Purity

- The availability of **reliable and internationally accepted methods** and of an appropriate **technical infrastructure** for **seed quality testing** are essential in the current scenario

Who Needs Seed Testing

- **Producers**
  - Want to be compliant
- **Users**
  - Need to know and to be sure
- **National Authorities**
  - Need to assure agreed level of quality

International Seed Testing Association

http://seedtest.org/en/home.html

What it is

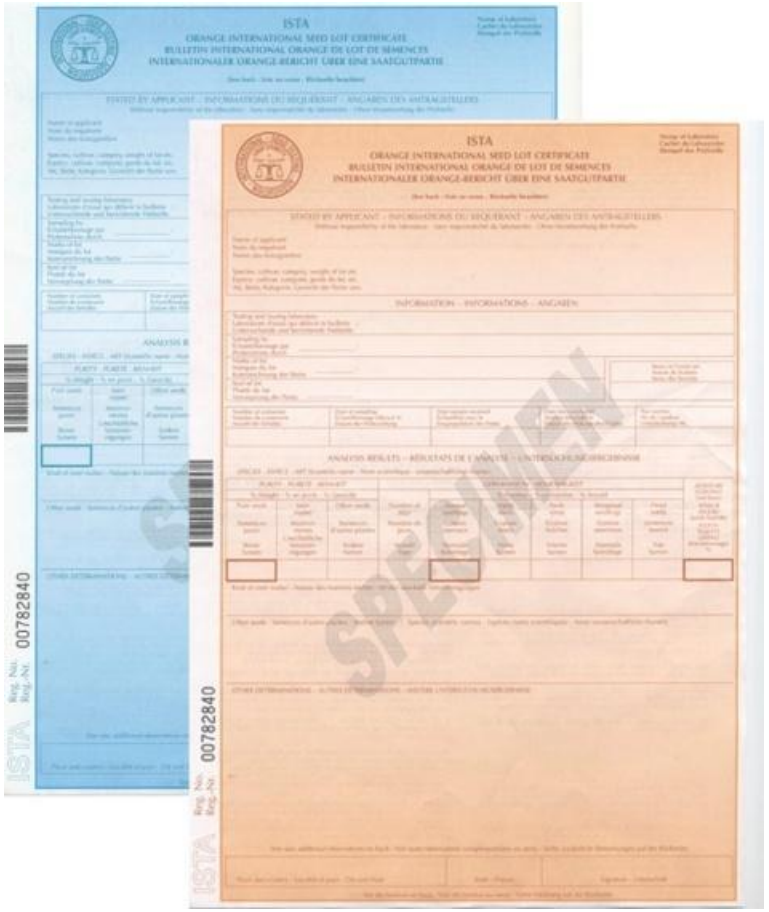
- Association of Laboratories, Personal and Technical Committee Members
- Based on non-profit cooperation
- Founded in 1924 at the 4th International Seed Testing Congress in Cambridge
- International Seed Testing Rules first issued in 1931

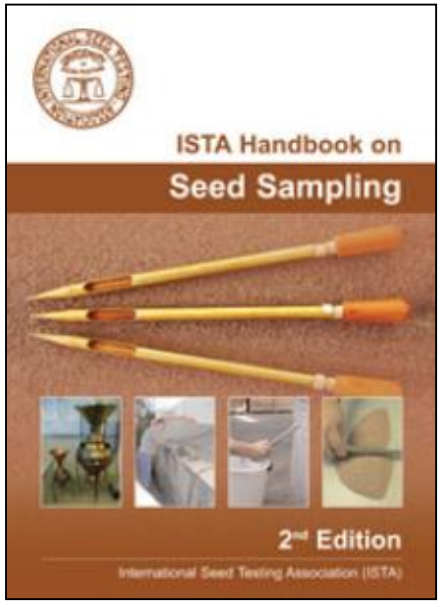
International Seed Testing Association

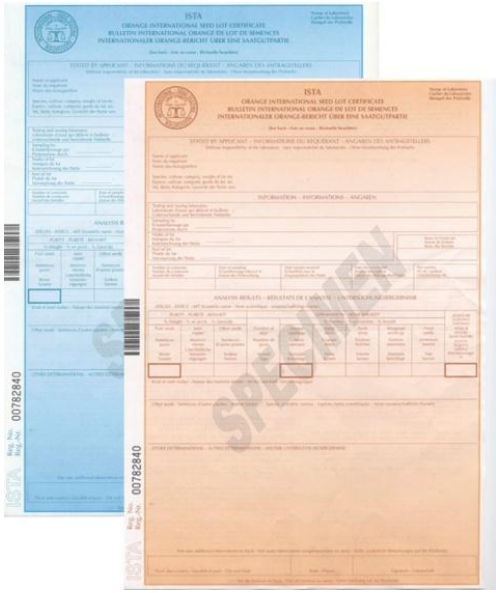
Goals

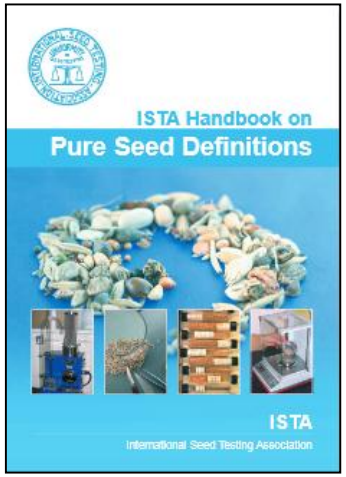
- Develop and publish standard procedures for sampling and testing seeds ➔ ISTA Rules
- Promote their uniform application for evaluation of seeds moving in international trade ➔ Lab. accreditation
- Support research in all areas of seed science and technology, including sampling, testing and processing ➔ Seed Symposia, "Seed Science and Technology", workshops
- Establish and maintain liaisons with other organizations having common interests in seed ➔ e.g. AOSA, EC, ESA, EU, FAO, ISF, OECD, UPOV and others….

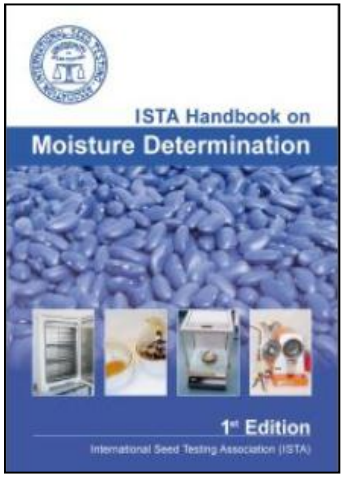

INTERNATIONAL SEED TESTING ASSOCIATION
UNIFORMITY IN SEED TESTING
International Rules for Seed Testing
INTERNATIONAL SEED TESTING ASSOCIATION

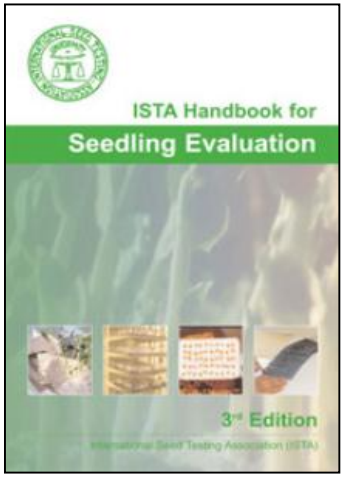

ISTA
ORANGE INTERNATIONAL SEED LOT CERTIFICATE
BULLETIN INTERNATIONAL ORANGE DE LOT DE SEMENCES
INTERNATIONALER ORANGE-BERICHT ÜBER EINE SAATGUTPARTIE
00782840
SPECIMEN











GMO testing Handbook

(in prep.)

International Seed Testing Association

Membership

- Global: ~200 labs in >75 countries, ~ 120 accredited
- >250 personal members
- Public sector: universities, governmental organizations
- Private sector: seed company and analytical labs
- ISTA values the diversity of its membership, as the basis for its independence from economic and political influence

Traditional ISTA Methods: Approval

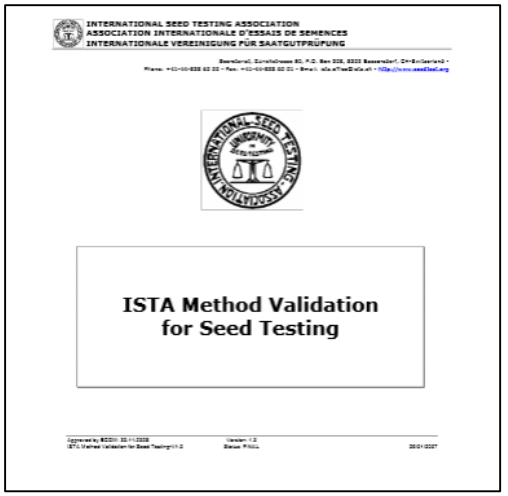
Test Method X is developed

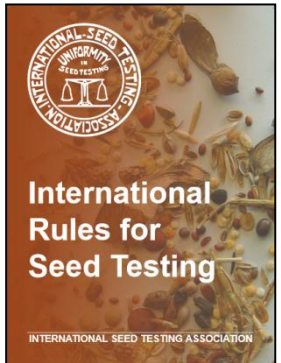
Validation study (interlaboratory) is planned and performed following the ISTA protocol

Validation Report is reviewed whether it meets the requirements

Rule proposal to the Membership Voting at the Annual Meeting

Method X is recognized as an official ISTA Method





…but a different approach was used for GMO testing…

- GM crops started in 1996 and at the turning of the millennium the **adventitious presence of GM seeds** in non-GM seed lots was felt as a threat for the seed trade

La STAMPA 03/07/2003

Mais all'Ogm: 381 ettari a rischio distruzione

Oggi la decisione, sarebbe la prima volta

La grande invasione dei prodotti biotech

Guariniello: nessuna clemenza per chi truffa i consumatori

13/07/2003

CORRIERE DELLA SERA

I trattori distruggono il mais transgenico

Piemonte, parte il piano per l' abbattimento. Alemanno: scelta inevitabile e coraggiosa Proteste tra i contadini. Il favorevole: ora passerò al biologico Indagata un' azienda di sementi per frode in commercio

DAL NOSTRO INVIATO PINEROLO (Torino) - C' è chi applaude, chi mugugna, chi grida vendetta. Chi ubbidisce e chi si ribella. L' operazione «tolleranza zero» sugli Ogm inaugurata dalla Regione Piemonte è partita ieri tra polemiche e approvazioni. Le associazioni di categoria sono spaccate: la Coldiretti, favorevole alla distruzione, annuncia che si costituirà contro le multinazionali che hanno prodotto il

- ISTA had to face the **urgent need** for suitable and reliable detection and quantification methodologies for GMO

Country	Value (USD million)	Country	Value (USD million)
USA	12,000	Morocco	140
China	9,950	Switzerland	140
France	2,800	Bulgaria	120
Brazil	2,625	Chile	120
Canada	2,120	Nigeria	120
India	2,000	Serbia	120
Japan	1,350	Slovakia	110
Germany	1,170	New Zealand	100
Argentina	990	Uruguay	96
Italy	767	Ireland	80
Turkey	750	Paraguay	80
Spain	660	Portugal	80
Netherlands	590	Algeria	70
Russian Federation	500	Kenya	60
United Kingdom	450	Iran	55
South Africa	428	Israel	50
Australia	400	Tunisia	45
Republic of Korea	400	Bolivia	40
Mexico	350	Colombia	40
Czech Republic	305	Slovenia	40
Hungary	300	Peru	30
China, Taiwan	300	Zimbabwe	30
Poland	280	Malawi	26
Sweden	250	Libya	25
Romania	220	Saudi Arabia	20
Denmark	218	Zambia	20
Greece	200	Philippines	18
Belgium	185	Ecuador	15
Finland	160	Tanzania	15
Austria	145	Uganda	10
Egypt	140	Dominican Republic	7
Total USD 44,925 million (2013 figures)			
The commercial world seed market is assessed at approx. USD 45 billion			

GMO Seed Testing is important

6 of the top 10 commercial markets for seed are growing Biotech crops

Data from:
ISF 2014
ISAAA 2014

(from Ray Shillito – Bayer)

However:

- **ISTA is international by definition** therefore it must represent the whole diversity of needs:
  - Adventitious Presence vs Trait Purity
  - Quantification as

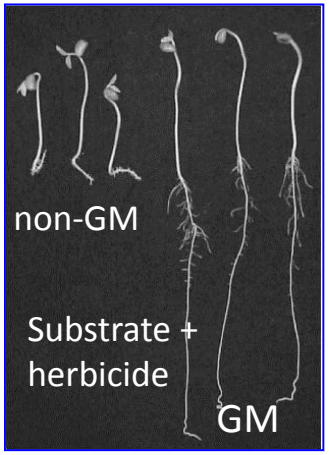
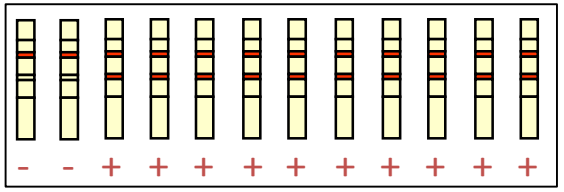
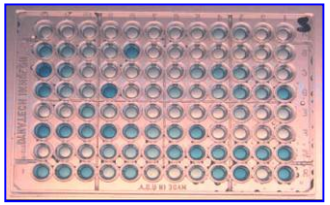
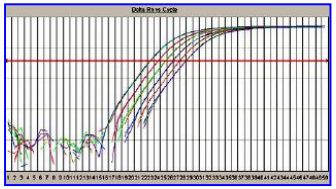
    % seed, % by mass, % copy number

- **Different techniques and approaches** worldwide:
  - Bioassays, immunoassays, PCR
  - Testing Single Seed, Groups (sub-sampling), Bulks (as with real time PCR)

- **Fast technological development**
  - Wide gap among labs in different regions

➔ international standardization difficult

Possible Workflows to Quantitation of Adventious presence or Trait Purity

Approach	Qualitative	Semi-quantitative (subsampling)	Quantitative
Working sample	 individual seeds	 n. seed groups (subsamples)	 1-few seed bulks
Method	 Bioassay	 *ep* PCR ↑ or immunoassay ↓ 	 ELISA ↑ or rt PCR ↓ 
Result	Quantitative Trait Purity or Adventitious Presence		

INTERNATIONAL SEED TESTING ASSOCIATION

APPROVED BY THE EXECUTIVE COMMITTEE OF ISTA
(Version 1, November 14, 2001 (update: July 11, 2011))

POSITION PAPER

ON

ISTA'S STRATEGY REGARDING METHODS FOR THE DETECTION, IDENTIFICATION AND QUANTIFICATION OF GENETICALLY MODIFIED SEEDS IN CONVENTIONAL SEED LOTS

https://www.seedtest.org/upload/cms/user/42Int-M-I200142ISTAPositionPaperonGMOapproved14112001-update1.pdf

- **Vision**
- **Strategy**
- **Action plan**

ISTA Position Paper on GMO - 2001

The Vision

ISTA labs are competent for both *Adventitious Presence* and *Trait Purity* providing uniform test results worldwide

Strategy

ISTA proposes a system targeting *uniformity in GMO testing results instead of uniformity in methods* by adopting a

Performance Based Approach (PBA)

Action Plan

- *Proficiency Test* program on GMO (since 2002)
- *Workshop* program (since 2001)
- Website (since 2007)
- Chapter on GMO in the ISTA Rules (since 2014)

PERFORMANCE BASED APPROACH
How does it work?

"Principles and Conditions for Laboratory Accreditation under the Performance Based Approach"

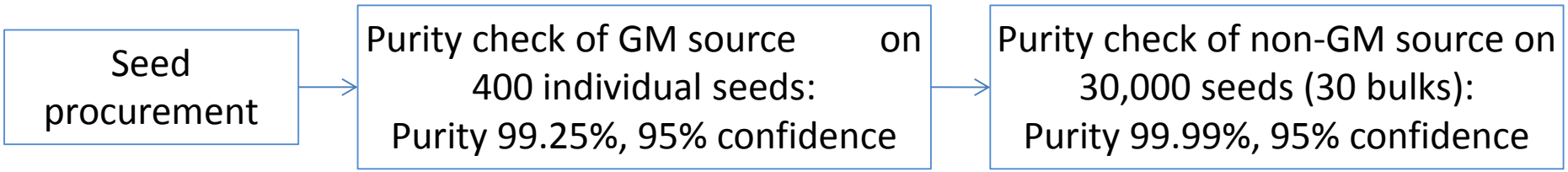
- A laboratory can have accreditation for a procedure not in the ISTA Rules
- **The procedure should be defined** in terms of: testing approach, technology used, basic methods, species tested and the specified trait to be determined
- **The basic method adopted is a method validated by an external body (e.g. CRL)** and verified within the lab
- Accreditation is granted only for methods for which the lab can demonstrate technical competence through:
  - **method performance data**
  - **proficiency test participation**
  - **on-site assessment (audit)**

PERFORMANCE DATA EVALUATION (PDE)

- For each procedure (i.e. approach/species/method/trait combination) within its scope of accreditation a lab must obtain performance data (PD)

- At least one full set of data per species, i.e. **starting from seed**

- Preliminary checks necessary



PERFORMANCE DATA EVALUATION (PDE)

- A grade is given to evaluate performance

For Detection (qualitative determination only)

- *Grade based on n. of samples correctly classified*

For Quantification

- *Accuracy*
- *Repeatability*

Grading General

Grade 1: No problem detected from experiment

Grade 2: Improvement is possible

Grade 3: Serious problem to be addressed

Performance Data Evaluation - Detection

30 blind samples prepared

10 samples of 400 seeds each containing 3 seeds with the specified trait (spiking level 0.75%)

Sample	1	2	3	4	5	6	7	8	9	10
Result	P	P	P	P	P	P	P	P	P	P

10 samples of 400 seeds each containing 2 seeds with the specified trait (spiking level 0.5%)

Sample	1	2	3	4	5	6	7	8	9	10
Result	P	P	P	P	P	P	P	P	P	P

10 samples of 400 seeds each containing NO seeds with the specified trait

Sample	1	2	3	4	5	6	7	8	9	10
Result	A	A	A	A	A	A	A	A	A	A

ISTA Seminar for Specified Trait Testing, 16 June 2006, Bologna, Italy INTERNATIONAL SEED TESTING ASSOCIATION (ISTA)

Grade 1: All 30 samples correctly classified
Grade 2: 1-2 samples wrongly classified
Grade 3: more than 2 samples wrongly classified

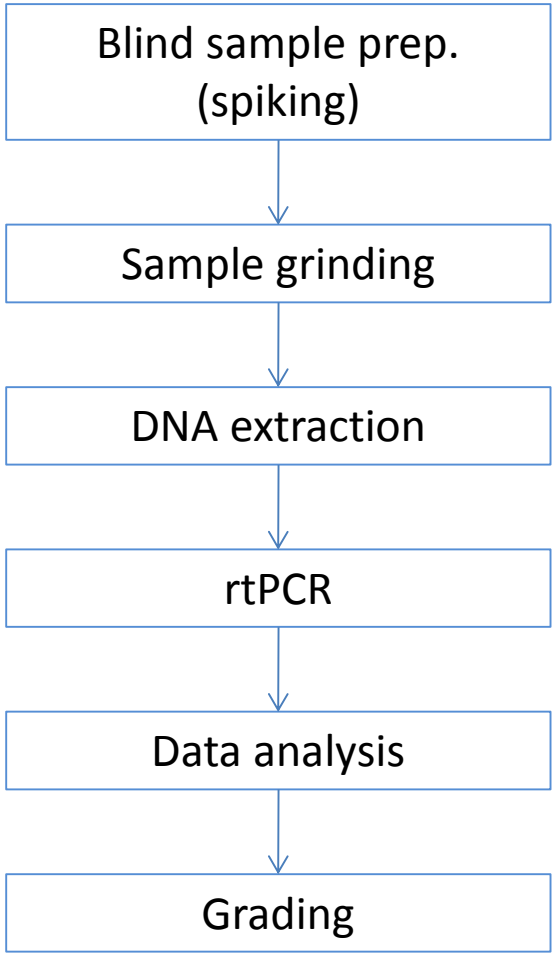
➔ *Grade 1 for Detection*

Performance Data Evaluation - Quantification

28 samples of 2000 seeds
7 spiking levels (as # of seeds)

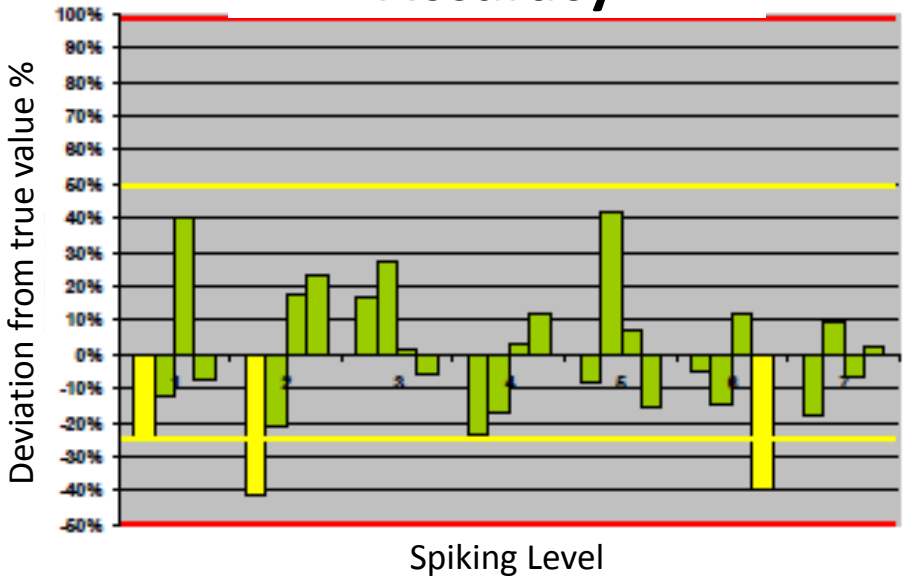
3 levels given
- 0.1% (2 spiked seeds)
- 0.5% (10 spiked seeds)
- 1.0% (20 spiked seeds)

4 levels (chosen by applicant)
- 0.1-0.5%
- 0.5-1.0%
- 1.0-2.0%
- 2.0-3.0%



Performance Data Evaluation - Quantification

Accuracy

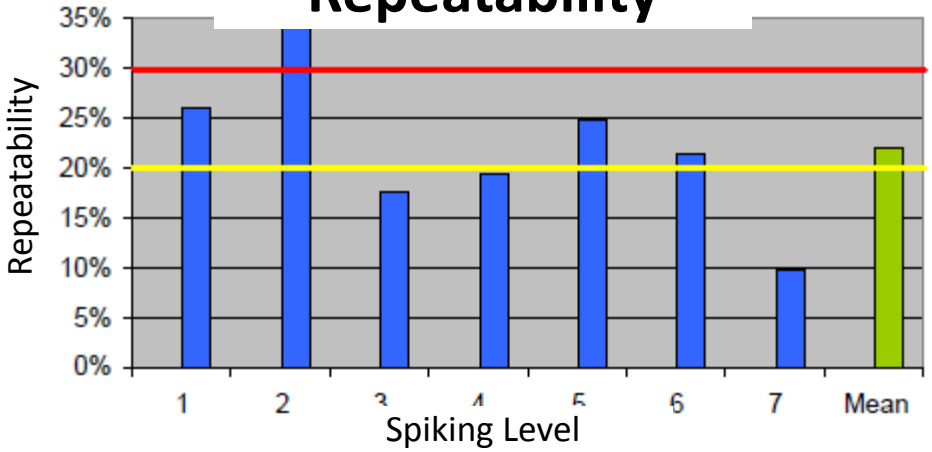


***Grade** based on deviation from true value*

1: All 28 samples accuracy within -0.25 and +0.5
2: No samples with accuracy lower than -0. 5 and +1
3: Some samples with accuracy lower than -0. 5 and +1

➔ *Grade 2 Accuracy*

Repeatability



***Grade** based on square root of the average of the variances per level*

1: Repeatability std-dev (%) below 20%
2: Repeatability std-dev (%) below 30%
3: Repeatability std-dev (%) greater than 30%

➔ *Grade 2 Repeatability*

ISTA GMO Proficiency Tests (PT)

- Participants must demonstrate their competence
- Obligatory if a lab has that species in his scope of accreditation
- Two rounds per year (as a rule)
- Samples consist of seeds
- Focussed on internationally important species and traits
- Include both detection and quantification
- Valid quantification: % seed, % mass, % copy number

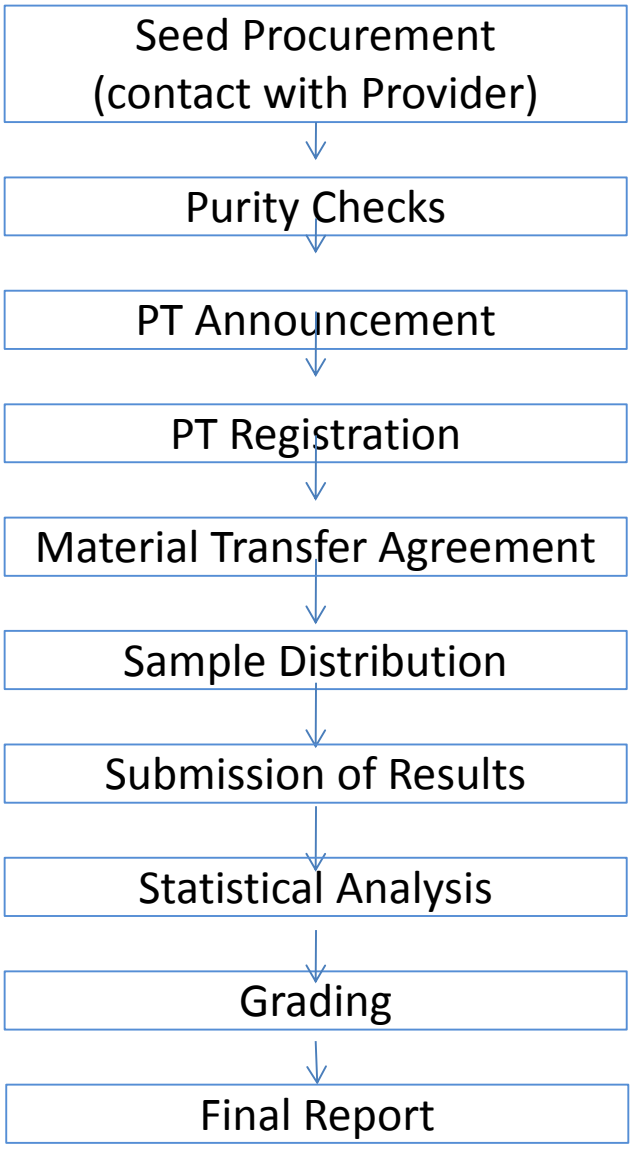
ISTA GMO Proficiency Test Program

PT-Round	Species	Event(s)	spiking levels (%)	# samples	# seeds /sample	# labs
PT01	Maize	T25/MON810	1.0	30	300	43
PT02	Maize	MON810	0.7 - 1.4	10	3000	48
PT03	Maize	T25/MON810	0.2 - 2.0 - 4.0	12	1500	40
PT04	Soybean	GTS40-3-2	0.1 - 0.5 - 1.0	12	3000	51
PT05	Soybean	GTS40/A2704	0.2 - 0.5 - 1.0 - 1.5	12	3000	58
PT06	Canola	GT73	0.3 - 0.6	10	3300	49
PT07	Maize	MON863, NK603	0 - 0.4 - 0.8 - 2.0	12	2000	57
PT08	Soybean	GTS40-3-2	0 - 0.13 - 0.5 - 1.0 - 2.3	14	3000	52
PT09	Maize	MON863, NK603	0 - 0.1 - 0.8	12	2000	56
PT10	Cotton	MON531, MON1445, MON 531xMON1445	0.6 - 0.8 - 1.2 - 1.4	12	2500	25
PT11	Canola	T45, RF3	0 -0.4 - 0.6 - 1.2 - 2	12	3000	43
PT12	Maize	Bt11, TC1507, T25	0 - 0.4 - 0.5 - 1.0 - 1.2 - 1.6	12	2000	54
PT13	Canola	T45, RF3	0 - 1.0 - 1.6 - 2.0 - 2.6	12	3000	30
PT14	Soybean	MON89688	0 - 0.3 - 0.6 - 1.0 - 1.2 - 2.0	12	3000	38
PT15	Linseed	FP967	0 - 0.13 - 0.2 - 0.8	8	1500	29
PT16	Maize	GA21	0 - 0.11 - 0.779 - 1.279	8	1800	45
PT17	Soybean	MON89688, GTS40-3-2	0 - 0.2 - 0.8 - 1.0	8	2000	44
PT18	Maize	GA21, NK603	0 - 0.08 - 0.68 - 1.64	8	2500	47
PT19	Soybean	MON89688, GTS40-3-2	0 - 0.11 - 0.555 - 1.455	8	1800	39
PT20	Cotton	GHB614, LLCotton25	0 - 0.4 - 0.8	8	2000	n.a.

ISTA GMO Proficiency Tests

The execution of a single round of the GMO PT Program is complex and involves significant organization, coordination, and administration from all parties involved in it's delivery.

ISTA is grateful to the seed Industry providing the materials and financial support for the organization



ISTA GMO Proficiency Tests

Rating: general

- **A** No problem has been detected in this test
- **B** Small problems but no specific action suggested
- **C** Problems, there is a need for a follow-up action and corrective measures
- **BMP** (Below Minimum Performance) Problems, lab must investigate and find explanation and mprove/correct

INTERNATIONAL SEED TESTING ASSOCIATION

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Final Results PT19

Participant # 23
Lab: GM.42

Species: Soybean
Event(s): Mon89788, GTS40-3-2

Accred. for Perf.Appr.Methods ☐ Participation oblig. ☐ 1035

Method Ident:
Method Quant: SS
Method Detect: PCR

Limit of Detection:
Limit of Quantification:

Estim. False Positive Rate:
Estim. False Negative Rate:

Rating detection (qualitative) A
0 mis-classified sample(s)

Rating quantification A
reference for rating: % number

Report Unit: % NUMBER

Sample Spiking Info

Sample	% mass GMO				% # GMO	qual result reported*					quant result reported					Note
	Total	GTS40	MON8978		Total	Total	GTS40	MON8978			Total	GTS40	MON8978			
1	0.00	0	0	0	0.00	0	0	0			0.00	0.00	0.00			
2	0.30	0.3	0	0	0.56	1	1	0			0.52	0.52	0.00			
3	0.94	0.56	0.38	0	1.44	1	1	1			1.52	1.10	0.42			
4	0.09	0	0.09	0	0.11	1	0	1			0.12	0.00	0.12			
5	0.00	0	0	0	0.00	0	0	0			0.00	0.00	0.00			
6	0.29	0.29	0	0	0.56	1	1	0			0.42	0.42	0.00			
7	0.09	0	0.09	0	0.11	1	0	1			0.12	0.00	0.12			
8	0.96	0.59	0.37	0	1.44	1	1	1			1.43	0.91	0.52			

* 1=positive, 0=negative

ISTA Workshops on GMO

Year	Workshop	Location
2001	ISTA/FAO varietal verification and GMO detection	Buenos Aires, Argentina
2003	ISTA/FAO Varietal Verification and GMO Detection	Pretoria, South Africa
2003	ISTA/FAO Varietal Verification and GMO Detection	Nakhon Pathom, Thailand
2004	ISTA/FAO Varietal Verification and GMO Detection	Pretoria, South Africa
2004	ISTA Statistical Aspects of GMO Detection - Europe	Toulouse, France
2004	ISTA Statistical Aspects of GMO Detection - USA	St. Louis, USA
2004	ISTA/FAO Varietal Verification and GMO Detection	Giza, Egypt
2004	ISTA/FAO Varietal Verification and GMO Detection	Ljubliana, Slovenia
2005	ISTA/FAO Varietal Verification and GMO Detection	Beijing, China
2005	ISTA Statistical Aspects of GMO Detection	Buenos Aires, Argentina
2005	ISTA/FAO Varietal Verification and GMO Detection	Kingston, Jamaica
2006	ISTA/FAO Varietal Verification and GMO Detection	Izmir, Turkey
2007	ISTA Laboratory and Statistical Aspects of GMO Detection	Izmir, Turkey
2007	ISTA Statistical Aspects of GMO Detection - USA	Iguassu, Brazil
2009	Workshop on Biotechnology Trait Detection	Osijek, Croatia
2009	The Analysis of Agricultural Products for the Presence of GMO	Tehran, Iran
2010	ISTA Varietal Verification and GMO Detection	Bangalore, India
2010	ISTA Workshop on GMO Testing	Oberschleissheim, Germany
2011	ISTA Workshop on Statistical Aspects of GMO Detection	Iztapalapa, México
2011	ISTA Workshop on Biotechnology Trait Detection	Shanghai, China
2012	ISTA GMO Auditors Workshop	Bologna, Italy

ISTA Workshops on GMO

•Usually offered upon request of a local member or non-member laboratory or a national or global organization

•Costs may be covered by participation fees, sponsorships or funding from various agencies

•The characteristics of the workshop depend on the request of the applicant

•They may deal with theoretical, technical, practical and statistical aspects, with varying compositions

•A “winning” format is the one where statistical and technical aspects are both present, simulating “real life” cases

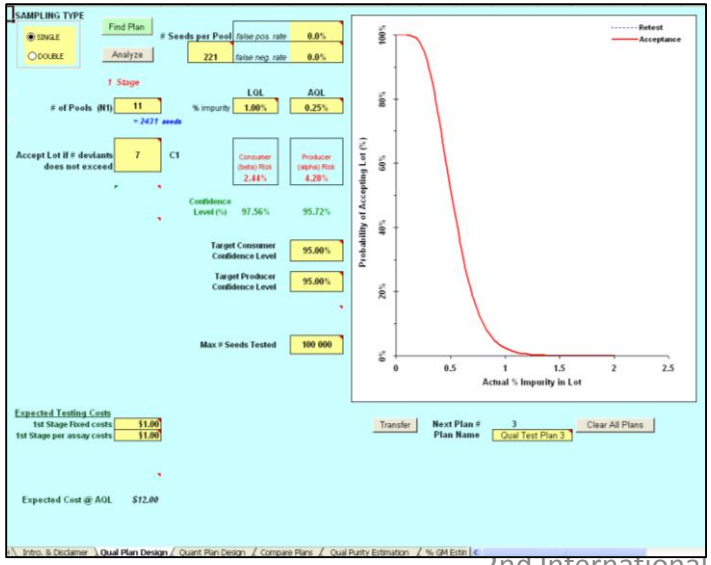
•Workshops are a great opportunity for fostering interesting discussions and exchange of information among all participants

ISTA Workshops on GMO

Both "Technical" and "Statisical"aspects are dealt with theoretically and "hands-on"

Technical aspects

- Objectives and methods of GM detection
- Sample preparation and DNA extraction, DNA quantitation and quality control
- End point and real time PCR, quality control in PCR analysis. Issues of quantification
- ISTA accreditation



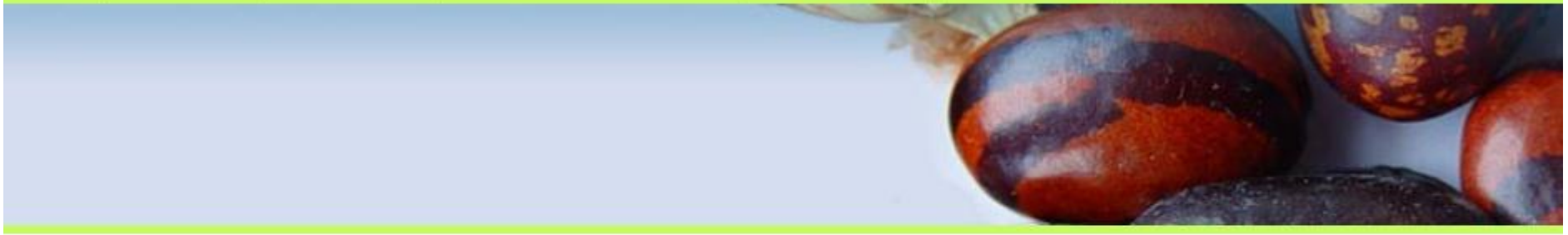
Statistical aspects

- Basic theoretical concepts: sample and population, tools to explore data, and probability distributions
- Analysis of Variance (ANOVA), repeatability and reproducibility and uncertainty estimation
- Statistical tools for designing and assessing testing plans and obtaining estimates (SeedCalc) also for stacked events

ISTA Website on GMO

ISTA Online

HOME | ABOUT ISTA | MEMBERSHIP | **TECHNICAL COMMITTEES** | ACCREDITATION | PUBLICATIONS | SEED TESTING LINKS



TCOMs / Info Platform

search

> contact > sitemap

Information Platform for GM Seed

Transgenic Event Descriptions | Analytical Methods | Statistical Tools | Reference Materials | Workshops | Accreditation for Specified Trait(s) | GMO Committee | Document | GMO Proficiency Tests

GM trait testing including the detection, identification and quantification of GM seeds is a relatively new area of seed quality testing that ISTA laboratories have become involved in.

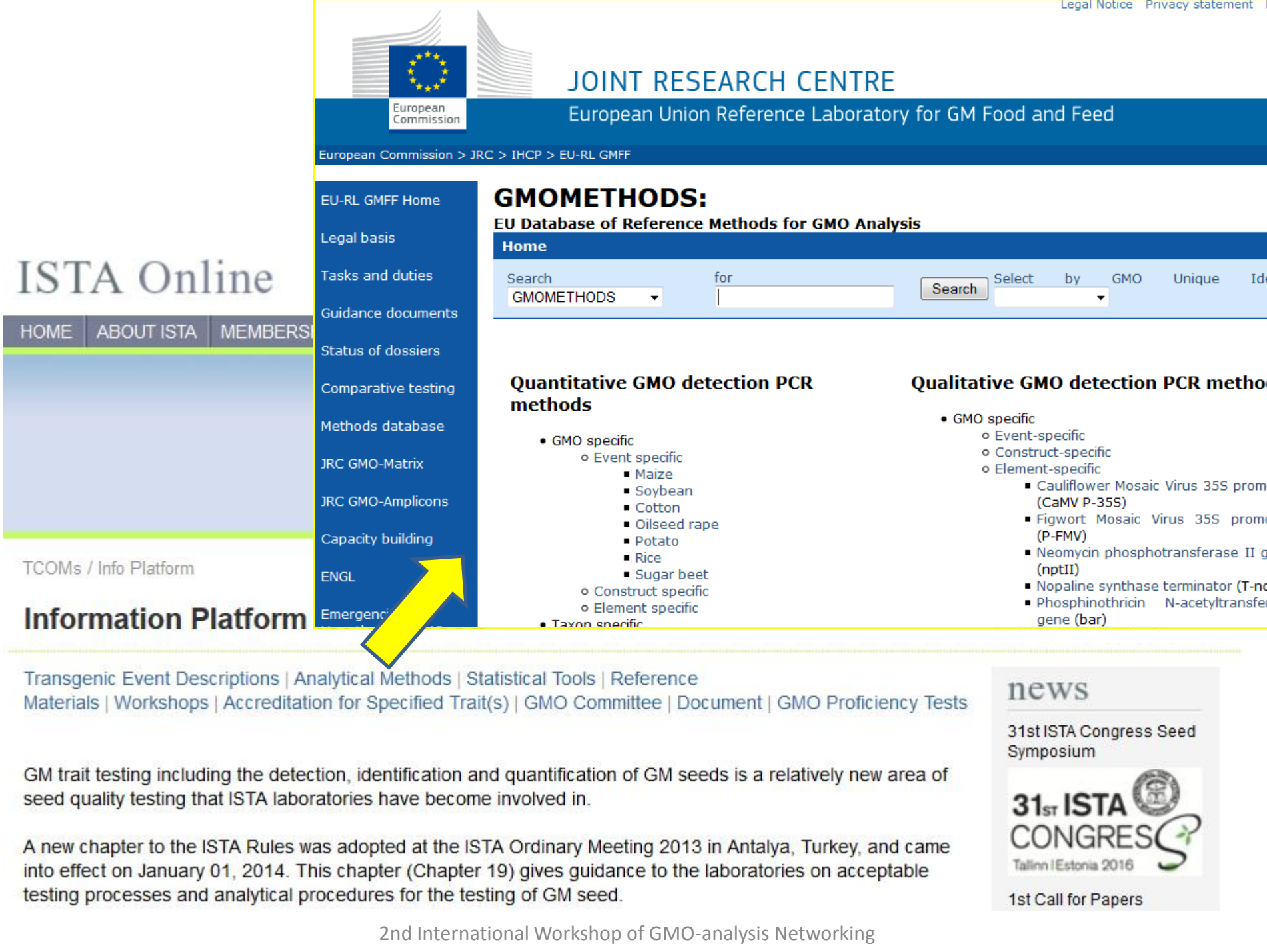
A new chapter to the ISTA Rules was adopted at the ISTA Ordinary Meeting 2013 in Antalya, Turkey, and came into effect on January 01, 2014. This chapter (Chapter 19) gives guidance to the laboratories on acceptable testing processes and analytical procedures for the testing of GM seed.

news

31st ISTA Congress Seed Symposium

31ST ISTA CONGRESS Tallinn | Estonia 2016

1st Call for Papers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Oilseed rape
Potato
Rice
Sugar beet
Construct specific
Element specific
Taxon specific
Qualitative GMO detection PCR metho
GMO specific
Event-specific
Construct-specific
Element-specific
Cauliflower Mosaic Virus 35S prom
(CaMV P-35S)
Figwort Mosaic Virus 35S promo
(P-FMV)
Neomycin phosphotransferase II g
(nptII)
Nopaline synthase terminator (T-nc
Phosphinothricin N-acetyltransfe
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ISTA Rules Chapter on GMO

Ch. 19 - Testing for Seeds of Genetically Modified Organisms

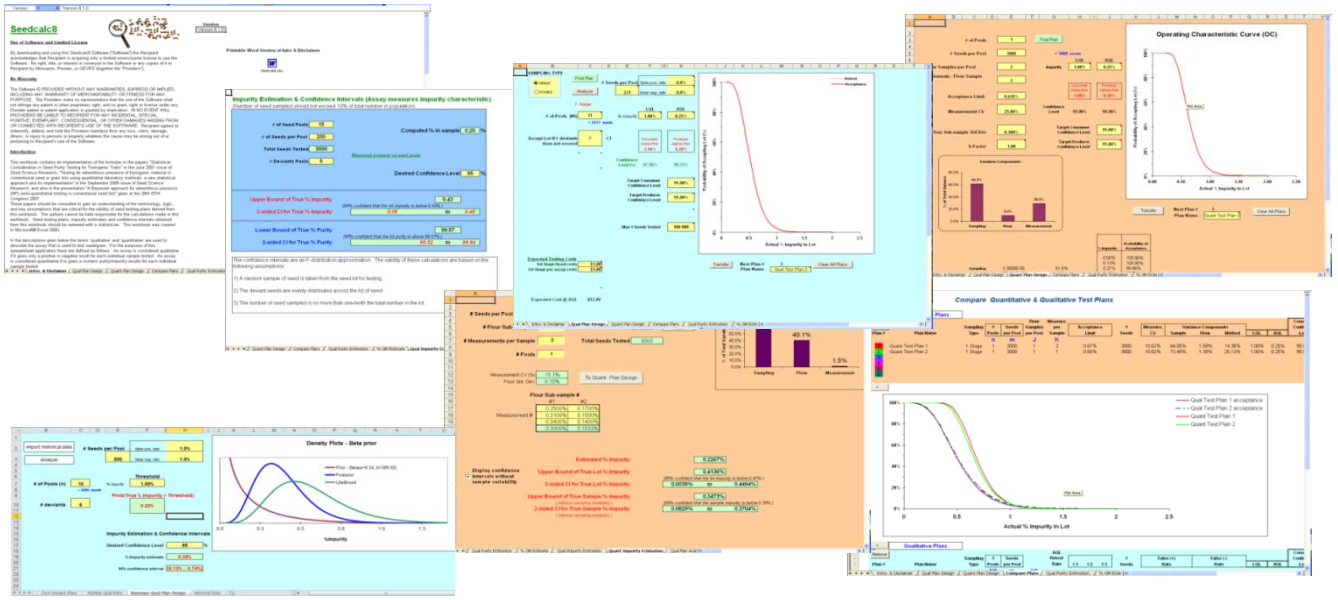
- 19.1 Object
- 19.2 Definitions
- 19.3 General principles
- 19.4 Procedure
- 19.5 Testing approaches
- 19.6 Calculation and expression of results
- 19.7 Reporting results
- 19.8 References

A **ISTA GMO Hand Book** is under development: to provide details of practical aspects on all subjects presented in Chapter 19

Statistical Tools for GMO Testing

The ISTA Statistics Committee has given a tremendous contribution to the progress of the work on GMO within ISTA (particular credit to J-L Laffont, K Remund and S Grégoire)

Seedcalc is an MS Excel file with different workbooks, each corresponding to a typical question regarding GMO testing in seeds



1. *Seedcalc – Qual Impurity Estimation* workbook

19.7 Reporting results

19.7.2 Quantitative results obtained by multiple qualitative tests of individuals or groups of seeds or seedlings

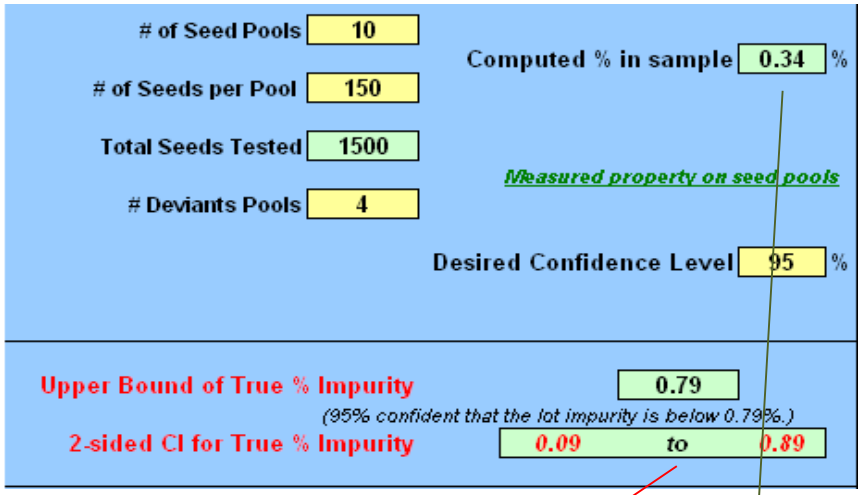
Results should be reported relative to the percentage of seeds or seedlings showing the test target specified by the applicant. The total number of seeds tested, the number of groups, and the number of seeds per group must be reported. Suggested phrases for reporting such results depending upon the result are as follows:

a) If the test target(s) was (were) not detected: 'The test target(s) was (were) not detected.'

b) If the test target(s) was (were) detected: 'The % of seeds in the lot with the test target(s) was determined to be …%, with a 95 % confidence interval of […%, …%].'

or

'For the test target(s) specified by the applicant, the seed lot meets the specification of ...% (maximum or minimum) with …% confidence.'



'The % of seeds in the lot with the test target(s) was determined to be **0.34**%, with a 95 % confidence interval of [**0.09**% , **0.89**%].'

1. *Seedcalc – Quant Impurity Estimation* workbook

19.7 Reporting results

19.7.3 Quantitative measurements of GMO in bulk samples

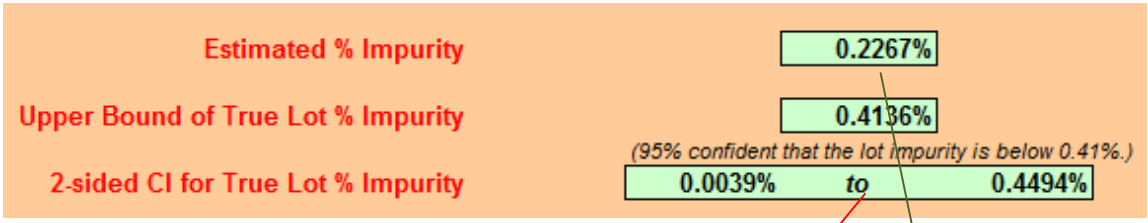
Results should be reported relative to the percentage of the test target specified by the applicant by mass or number of DNA copies. The testing plan (e.g. number of replicate seed samples, number of replicate flour samples per seed sample, number of extracts per flour sample, number of replicate measurements per extract) must be indicated.

Required phrases for reporting depending upon the results are as follows:

a) If the test target was not detected (no signal or below the limit of detection): 'The test target was not detected at a level above the limit of detection.'

b) If the test target was detected at a level above the limit of detection and below the limit of quantification: 'The test target was detected at a level below the limit of quantification of the method used.'

c) If seeds showing the test target were found at a level above the limit of quantification: 'The test target(s) percentage in the seed lot was determined to be ...% by mass or number of copies, with a 95 % confidence interval of [...%,...%]'
or
'For the test target(s) specified by the applicant, the seed lot meets the specification of ...% (maximum or minimum) by mass or number of copies with ...% confidence.'



'The test target(s) percentage in the seed lot was determined to be **0.23**%, with a 95 % confidence interval of [**0.004**% , **0.45**%].'

ISTA GMO Committee

#	Name	Country
1	Cheryl Dollard (Chair)	Canada
2	René Mathis (Vice –chair)	France
3	Christoph Haldemann (Past-chair)	Switzerland
4	Elizabeth Bates	Belgium
5	Sofia Ben Tahar	France
6	Tajinder Grewal	Canada
7	Lutz Grohmann	Germany
8	Andrea Jonitz	Germany
9	Jean-Louis Laffont	France
10	Enrico Noli	Italy
11	Elena Perri	Italy
12	Kirk Remund	United States
13	Guy Van den Eede - Resigned 2014	Italy
	Marco Mazzara – New Member!!!	European Commission
14	Ana Laura Vicario	Argentina
15	Bruno Zaccomer	France
16	Dabing Zhang	China
17	Ray Shillito	United States

ISTA GMO Committee

#	Working Groups	Lead	Work Description and Projects
1.1	GMO Proficiency Test: Administration and Sample Preparation	ISTA TCORD Nadine Ettel	Execution of the GMO PT
1.2	GMO Proficiency Test: Resource Procurement	Ray Shilito	Resource procurement in support of the GMO PT Program
1.3	Workshops	Cheryl Dollard	Delivery of training workshops in GMO Testing
1.4	ISTA GMO Website	Elizabeth Bates	To work to develop proposed content for the GMO TCOM Webpage
1.5	ATC contact	A.-L. Vicario	Purpose: Committee contact for the Advanced Technologies Committee
1.6	Statistical tools for GMO Testing	Jean-Louis Laffont	Statistical support of the Committee
1.7	Publications	Bruno Zaccomer	Coordination of writing of technical publications
1.8	Rules-Handbook	René Mathis	To develop New Rules Chapter and accompanying Technical Handbook for GMO Testing

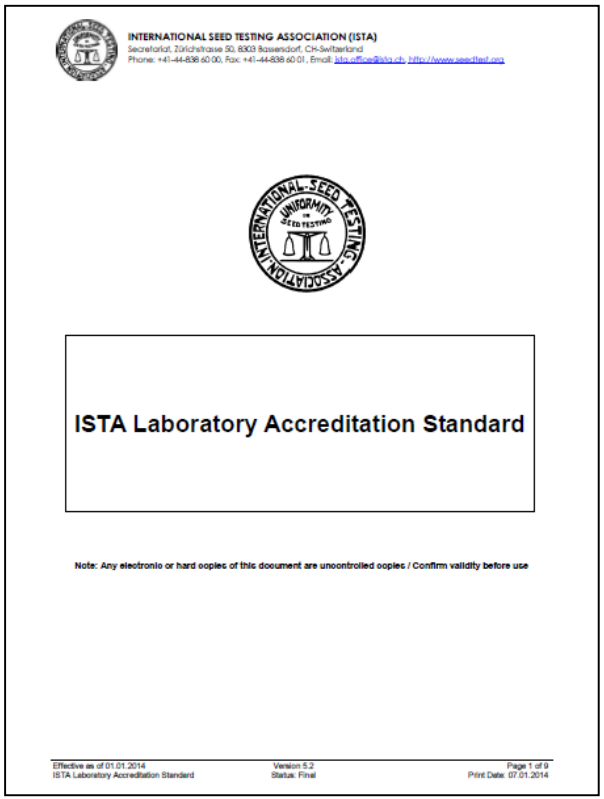
Thanks for your attention!

http://seedtest.org/en/home.html

ISTA Laboratory Accreditation Standard

(based on ISO 17025)

Specifies the **criteria** which must be fulfilled by laboratories in order **to obtain and maintain** their **accreditation to ISTA** and their authorisation to issue ISTA certificates



INTERNATIONAL SEED TESTING ASSOCIATION (ISTA)
Secretariat, Zürichstrasse 50, 8303 Bassersdorf, CH-Switzerland
Phone: +41-44-838 60 00, Fax: +41-44-838 60 01, Email: ista.office@ista.ch, http://www.seedtest.org

ISTA Laboratory Accreditation Standard

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Effective as of 01.01.2014 | Version 5.2 | Page 1 of 9
ISTA Laboratory Accreditation Standard | Status: Final | Print Date: 07.01.2014

1. Purpose and Scope
2. Definitions
3. Management Requirements
4. Staff
5. Environment, Equipment and Calibration
6. Lot ID, sampling and their handling
7. Methods and Procedures
8. Test Reports and Certificates
9. Documents and Records
10. Quality Assurance System

ISTA GMO Proficiency Tests

Rating: Detection

Rate	Percent of missclassified samples	Ex.: 12 samples
A	from 0% to 5%]	0
B	>5% to 10%]	1
C	>10% to 20%]	2
BMP	more than 20%	3 and more

Under revision

- Connection with Chapter **19** (Testing for seeds of GMOs) of the ISTA Rules:

19.7 Reporting results

19.7.3 Quantitative measurements of GMO in bulk samples

Results should be reported relative to the percentage of the test target specified by the applicant by mass or number of DNA copies. The testing plan (e.g. number of replicate seed samples, number of replicate flour samples per seed sample, number of extracts per flour sample, number of replicate measurements per extract) must be indicated.

Required phrases for reporting depending upon the results are as follows:

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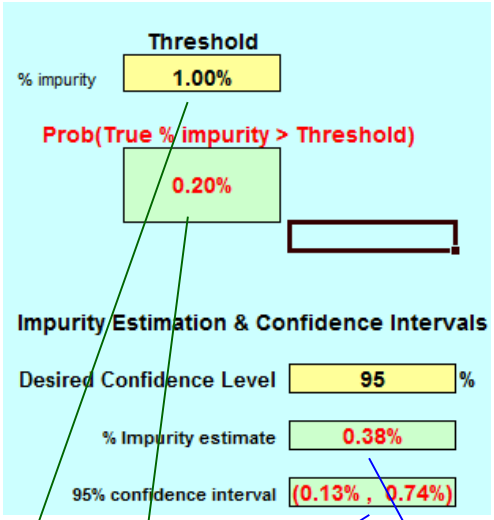
b) If the test target was detected at a level above the limit of detection and below the limit of quantification: 'The test target was detected at a level below the limit of quantification of the method used.'

c) If seeds showing the test target were found at a level above the limit of quantification: 'The test target(s) percentage in the seed lot was determined to be ...% by mass or number of copies, with a 95 % confidence interval of [...%,...%]'
or
'For the test target(s) specified by the applicant, the seed lot meets the specification of ...% (maximum or minimum) by mass or number of copies with ...% confidence.'



'The test target(s) percentage in the seed lot was determined to be **0.38**%, with a 95 % confidence interval of [**0.13**% , **0.74**%].'

'For the test target(s) specified by the applicant, the seed lot meets the specification of **1**% (maximum) by mass or number of copies with **99.8**% confidence.'

- Connection with Chapter **19** (Testing for seeds of GMOs) of the ISTA Rules:

19.7 Reporting results

19.7.3 Quantitative measurements of GMO in bulk samples

Results should be reported relative to the percentage of the test target specified by the applicant by mass or number of DNA copies. The testing plan (e.g. number of replicate seed samples, number of replicate flour samples per seed sample, number of extracts per flour sample, number of replicate measurements per extract) must be indicated.

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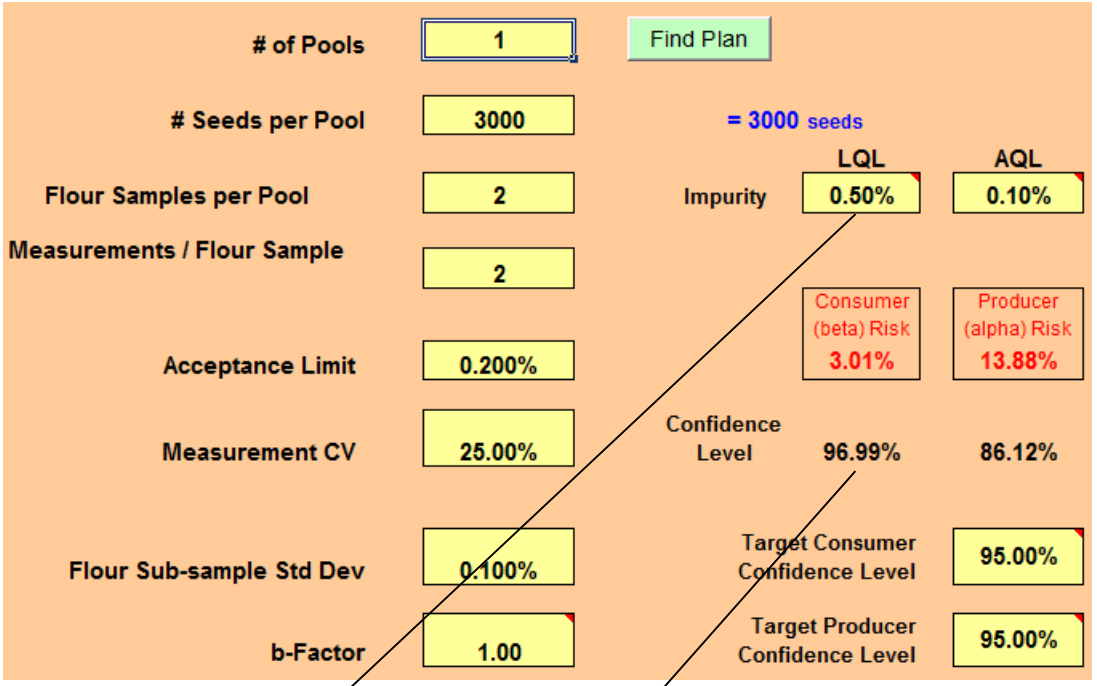
or

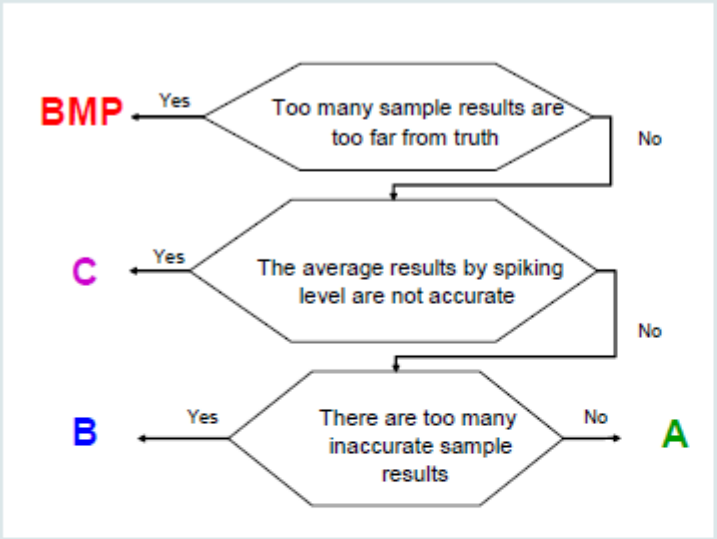
'For the test target(s) specified by the applicant, the seed lot meets the specification of …% (maximum or minimum) by mass or number of copies with …% confidence.'



'For the test target(s) specified by the applicant, the seed lot meets the specification of **0.50**% (maximum) by mass or number of copies with **96.99**% confidence.'

ISTA GMO Proficiency Tests

Rating: general



Principles

Decision rules