

A young boy with short brown hair, wearing a red t-shirt, is shown in profile, looking intently at a glowing jar he is holding with both hands. The jar contains a glowing yellow DNA double helix structure. The background is a dark, starry night sky with soft, out-of-focus lights. The overall mood is one of wonder and scientific discovery.

Welcome

Non-pathogen and pathogen molecular training session

1

Topic 1: Food Authenticity

2

Topic 2: Species ID

3

Topic 3: Ethical Claims (Halal/ Vegan)

4

Topic 4: Pathogens & automation



Food Authenticity

The labeling of food products is essential to inform consumers what kind of products they are buying. EU harmonised rules on food labeling, presentation and advertising aim to protect consumers and facilitate trade inside and outside Europe.

Recently an initiative of the European Parliament (EP) has identified a number of foods such as: **olive oil, fish, honey, dairy products and meat** as being the target of fraudulent activities. This initiative calls for the development of technologies and methods to detect food fraud.



Food authenticity

What does it mean?

- **Food Fraud:** *intentionally causing a mismatch between food product claims and food product characteristics.*
- **Food Quality:** Historically, quality has been primarily understood as the absence of a defect, fraud and adulteration.
 1. expected properties such as organoleptic and nutritional characteristics or resulting benefits.
 2. desirable characteristics likely to justify added value; for example, forms of production (organic farming, environmental consideration, and animal welfare), production areas (designation of origin) and their associated traditions.



What can we test?

Food Quality and Authenticity

- Adulteration in meat, fish and dairy
- Labelling requirements for Vegan and Halal Food
- Presence/ absence and quantification of GMO on Food and feed.



Species ID detection



When is testing useful?

- Control of Food Fraud / Food Adulteration that costs million of \$ every year
- Comply to Country specific legislation for importing meat and fish products
- Ensure quality of raw material in processed Food
- Ensure customers special preferences: avoid allergic reactions, personal needs and religious concerns



Food & Feed industry



Trading companies



Private and Public Food laboratories



Customer Preferences

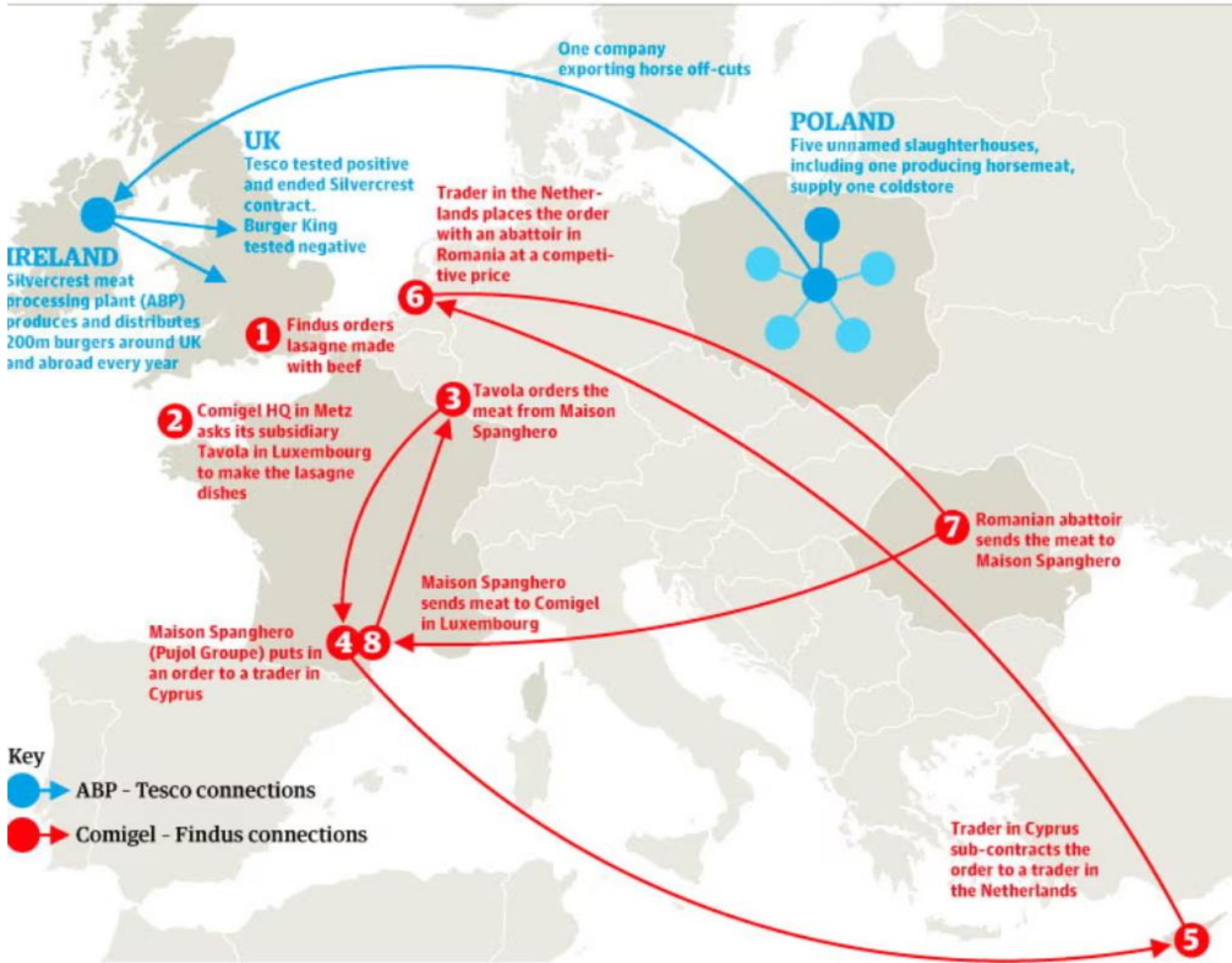
Legislative Landscape

European Union

- Current EU legislation on the labelling, presentation and advertising of food states that consumers must not be misled. It also requires that, in general, **all ingredients are listed in descending order of weight**. From 13 December 2014, new rules will replace this legislation and, among other provisions, will extend country of origin labelling (COOL) to meat from pigs, poultry, sheep and goats. COOL is mandatory for beef and some other products, including olive oil and honey.

Some History...

Britain's horsemeat The ABP and Comigel connections



Rapid Alert System for Food and Feed (RASFF) - Food Safety

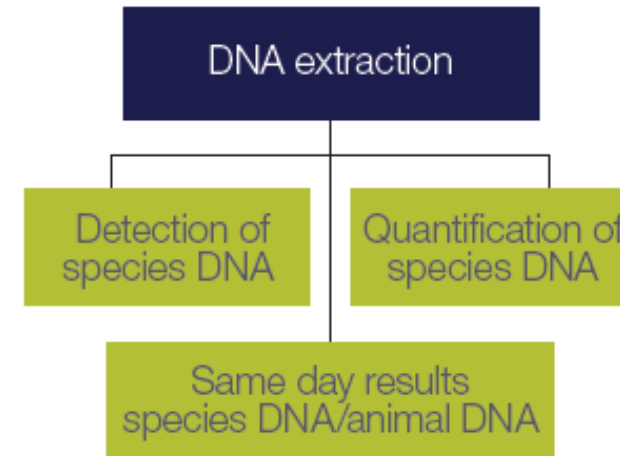
- ➔ Problems with unauthorized frozen tuna block vessels. Origin USA
- ➔ Labeling problems with fish from South Africa
- ➔ Problems with canned tuna from Ecuador
- ➔ Salmon transported in an unauthorized manner

- ⊕ Ruminant DNA detected in fish feed from Peru. Belgium 2023.
- ⊕ Ruminant DNA in protein concentrate for compound feed for pigs from Latvia. Lithuania 2023.
- ⊕ Possible presence of **pork** (extract) in Instant Noodle Soup from China. Netherlands 2023
- ⊕ Ruminant DNA in fish feed. Cyprus 2022.
- ⊕ Mismatched species in **squid** from India. Spain 2022
- ⊕ Improper health certificate(s) (species mismatch) for frozen baby **squid** (*Loligo chinensis*) from China. Spain 2022
- ⊕ Ruminant protein DNA in pork hemoglobin from Germany. Poland 2022



Reliable Detection and Quantification of Species DNA

- Full workflow solution**
 - DNA extraction options for low and high sample input
- High sensitivity**
 - Detection of mitochondrial DNA
- Quantitative**
 - Quantification based on DNA standards
 - Species DNA/total animal DNA result (%)



Extraction

Thermo Scientific™
GMO Extraction Kit



Detection

Thermo Scientific™
RapidFinder™ ID Kits



Quantification

Thermo Scientific™
RapidFinder™ Quant Sets



Thermo Scientific GMO Extraction Kit

A versatile method

COMPETITIVE ADVANTAGE

- Large amount of sample processed
- Minimized PCR inhibitors
- Maximized DNA yield
- High purity DNA (A260 / A280 > 1.8)

5-20 g versus 0.1-1 g (most kits)

Specifications	
Format	Spin Column
Isolation Technology	Silica Spin Column
Sample Type	Food and Environmental, Fungi, Plant, Yeast
Final Product Type	Genomic DNA
For Use With (Application)	Real-Time Quantitative PCR (qPCR), Sequencing, PCR
High-throughput Compatibility	Not High-throughput Compatible (Manual)
No. of Reactions	50 Isolations
Quantity	50 preps
Target	Genomic DNA
Test Time	2 hrs
Yield	100 ng/μL
Starting Material Amount	5-20 g
Unit Size	50 preps

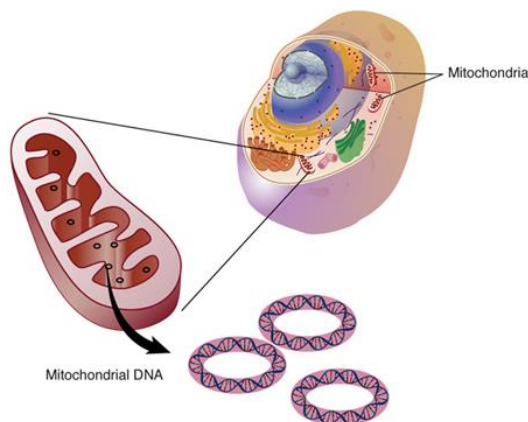


The Thermo Scientific™ RapidFinder™ kits

The Basics



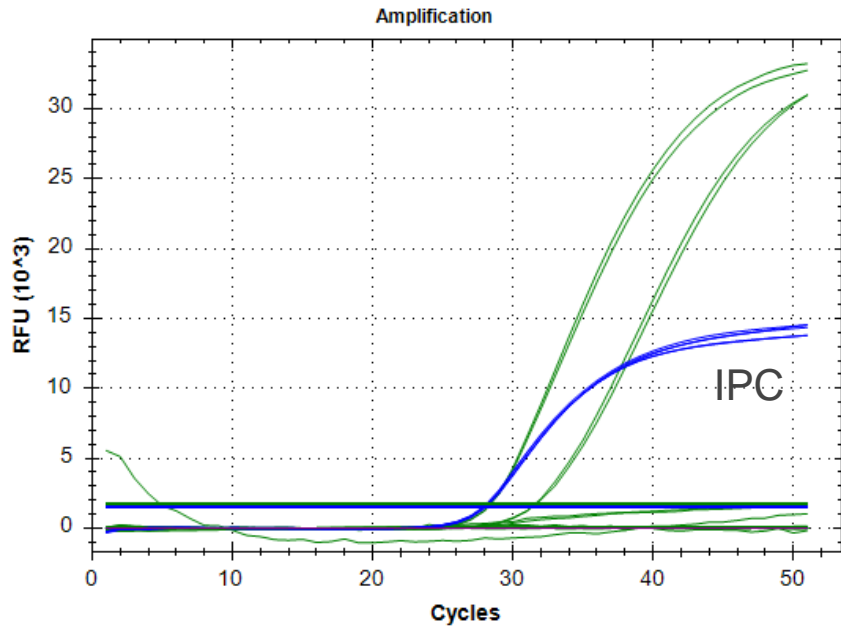
Species
ID



Qualitative and **Quantitative** determinations of animal species content in raw and processed material

- PCR detection of a highly conserved mitochondrial genomic region from animal species
- Sensitivity
 - Animal cells can contain 100s of mitochondria
 - Limit of detection of 0.01% (w/w) in fresh meat
- Specificity
 - Regulatory regions in the mitochondrial genome vary greatly between species

The Thermo Scientific™ RapidFinder™ kits



- ✓ **Internal Positive Controls (IPC)**
Multiplexed reagents to detect the presence of PCR inhibitors in the sample and confirm the correct functioning of the PCR.
- ✓ **Positive Controls**
Reference material containing 0.1% of the target species.

Confidence in your results



imegenagro

The Thermo Scientific™ RapidFinder™ multi-meat Quant kit

The RapidFinder™ Quant Multi-Meat Set is designed for use with one of the following compatible kits for real-time PCR detection of DNA for the meat species of interest.

- RapidFinder™ Beef ID Kit (Cat. No. A24391)
- RapidFinder™ Pork ID Kit (Cat. No. A24392)
- RapidFinder™ Halal ID Kit (Cat. No. A47086)
- RapidFinder™ Poultry ID Kit (Cat. No. A24397)
- RapidFinder™ Chicken ID Kit (Cat. No. A24393)
- RapidFinder™ Turkey ID Kit (Cat. No. A24394)
- RapidFinder™ Equine ID Kit (Cat. No. A15570)
- RapidFinder™ Sheep ID Kit (Cat. No. A24395)
- RapidFinder™ Goat ID Kit (Cat. No. A24407)
- RapidFinder™ Fallow Deer ID Kit (Cat. No. A24410)

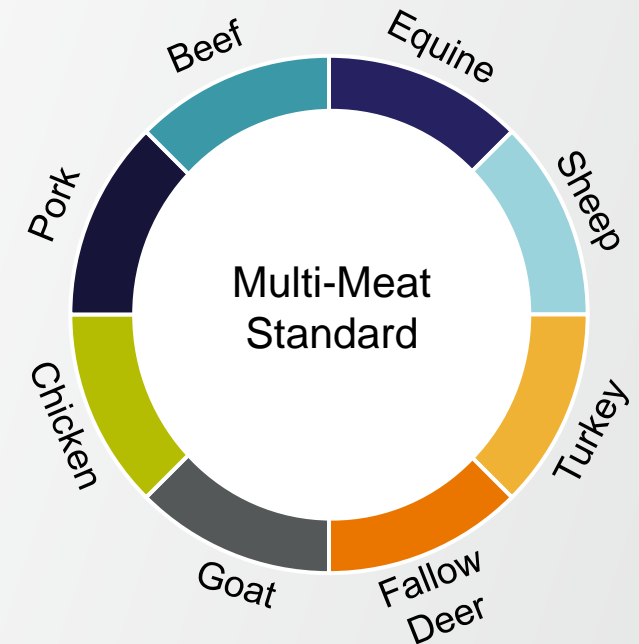


The Thermo Scientific™ RapidFinder™ multi-meat Quant kit

Allows the identification and quantification of meat species that are present in food samples as an essential step for verification of origin and traceability of raw materials, as well as for quality control of handling and cleaning processes in production lines.

The RapidFinder™ Quant Multi-Meat Set enables relative quantification of as little as 0.05% of specific animal species DNA with respect to total animal DNA in a sample. The kit includes:

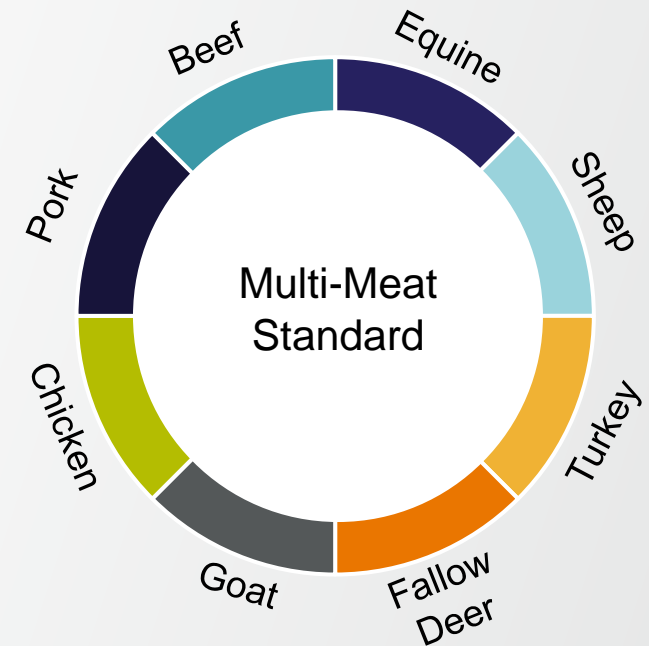
- Primers and TaqMan™ probe for real-time PCR detection of a highly conserved mitochondrial genomic region from animal species (total animal DNA target), for total animal DNA detection.
- Multi-Meat Standard, a plasmid DNA quantitation standard containing the total animal DNA target and each of the individual animal species targets used during analysis.
- Enzyme and other buffer components necessary for real-time PC



The Thermo Scientific™ RapidFinder™ multi-meat Quant kit

To quantify the percentage of species-specific DNA:

1. Two real-time PCR series are performed.
 - One detects the species-specific DNA of interest, using primers and TaqMan™ probe from the appropriate compatible RapidFinder™ Meat ID Kit.
 - One detects the total animal DNA target, using primers and TaqMan™ probe from the RapidFinder™ Quant Multi-Meat Set.
2. Each PCR series includes a dilution series of the Multi-Meat Standard in addition to the unknown samples and controls.
3. For each sample, species-specific and total animal DNA are quantified, relative to the Multi-Meat Standard.
4. The percentage of species-specific DNA with respect to total animal DNA is then calculated for that sample.



$$\% \text{ Species DNA} = \frac{\text{species DNA}}{\text{total animal DNA}} \times 100$$

The Thermo Scientific™ RapidFinder™ Product Range



RapidFinder™ Basa ID Kit	A24406	FISH ID
RapidFinder™ Gadus ID Kit	A24402	FISH ID
RapidFinder™ Haddock ID Kit	A24405	FISH ID
RapidFinder™ Pollack ID Kit	A24404	FISH ID
RapidFinder™ Pollock ID Kit	A24403	FISH ID
RapidFinder™ Specific Tuna ID Kit	A24411	FISH ID
RapidFinder™ Tuna ID Kit	A24415	FISH ID
RapidFinder™ Beef ID Kit	A24391	MEAT ID
RapidFinder™ Chicken ID Kit	A24393	MEAT ID
RapidFinder™ Duck ID Kit	A24413	MEAT ID
RapidFinder™ Equine ID Kit	A15570	MEAT ID
RapidFinder™ Fallow Deer ID Kit	A24410	MEAT ID
RapidFinder™ Goat ID Kit	A24407	MEAT ID
RapidFinder™ Pork ID Kit	A24392	MEAT ID
RapidFinder™ Rabbit ID Kit	A24408	MEAT ID
RapidFinder™ Sheep ID Kit	A24395	MEAT ID
RapidFinder™ Turkey ID Kit	A24394	MEAT ID
RapidFinder™ Water Buffalo ID Kit	A24414	MEAT ID
RapidFinder™ Poultry ID Kit	A24397	SCREENING TEST
RapidFinder™ Fish ID Kit	A24398	SCREENING TEST
RapidFinder™ Halal ID Kit	A47086	SCREENING TEST
RapidFinder™ Ruminant ID Kit	A24396	SCREENING TEST
RapidFinder™ Vegan ID Kit	A24412	SCREENING TEST
RapidFinder™ Quant Equine Set	A15579	QUANTIFICATION KIT
RapidFinder™ Quant Multi-Meat Set	A24399	QUANTIFICATION KIT

**Large range of Meat and Fish
 Identification Kits**
**Flexible quantification
 Screening Kits**

Competitive Landscape



Company	Thermo Fisher Scientific					
Brand	RapidFinder					
Methodology	qPCR	Immunistick	Multiplex qPCR	qPCR	qPCR	qPCR
Targets	Meat and Fish	Meat	Meat	Meat	Meat ID	Meat and Fish
Target breadth	7 fish, 11 animal, 5 screening and 2 quant				9 animal only qualitative	6 animal only qualitative
Quantification	Meat quantification kit : 9 species – to 0.5% Pork Quantification kit		4-plex target kits for quantification			
LOD						

RapidFinder has the largest selection of kits with the lowest LOD

Ethical Claims Halal – Vegan Assay



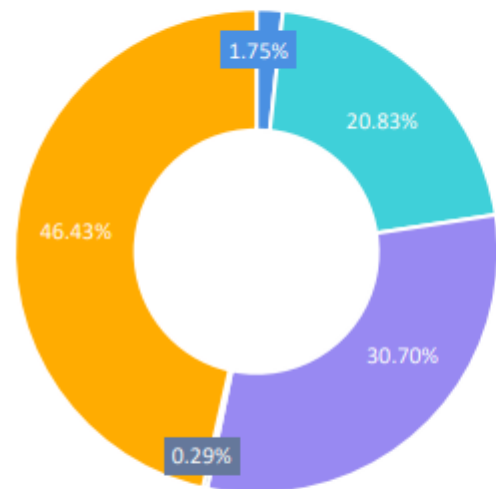
Halal Foods

- Food products prepared according to Muslim law
- Halal is an Arabic word that literally means 'permissible'
- Related to food, this means food which is permissible according to Islamic Law
- To make meat halal the following is required:
 - The animal or poultry must have been slaughtered in a ritual way
 - Swine is forbidden



Global Halal Market by Geography

HALAL MEAT MARKET, REVENUE SHARE (%), BY GEOGRAPHY, GLOBAL, 2022



- North America
- Europe
- Asia-Pacific
- South America
- Middle East & Africa

HALAL MEAT MARKET, REVENUE IN USD BILLION, BY GEOGRAPHY, GLOBAL, 2018-2030

GEOGRAPHY	2018	2019	2020	2021	2022	2023 (est.)	2030 (f)	CAGR (%) (2023-2030)
North America	2,470.1	2,545.8	2,627.4	2,712.7	2,803.3	2,904.9	3,789.5	3.87%
Europe	29,447.8	30,360.9	31,239.6	32,320.3	33,409.3	34,632.9	45,902.0	4.11%
Asia-Pacific	42,497.1	44,011.1	45,622.9	47,398.0	49,235.7	51,270.6	70,158.4	4.58%
South America	416.1	429.2	442.7	457.3	472.9	490.2	643.2	3.96%
Middle East & Africa	64,491.1	66,744.3	69,164.7	71,718.0	74,461.9	77,521.0	1,04,971.9	4.43%
Total	1,39,322.1	1,44,091.4	1,49,097.3	1,54,606.2	1,60,383.1	1,66,819.8	2,25,465.0	4.40%

HALAL CERTIFICATION INTRODUCING A NEW CONSUMER BASE

- **Rising Consumer Demand:** Halal certification is increasingly important for consumers, ensuring products meet Islamic laws and high-quality standards, thereby introducing a new consumer base for companies.
- **Quality and Spiritual Concerns:** Consumers in Muslim-populated countries (e.g., Pakistan, Indonesia, India, Malaysia, Iran) are concerned about food quality and origin, making halal certification crucial. Packaging also influences purchase behavior, as seen with Crescent Foods' new packaging.
- **Broad Appeal:** Non-Muslim consumers prefer halal products for ethical treatment, purity, and food safety. Halal certification boosts consumer confidence, appealing to a wide range of consumers.
- **Competitive Edge:** Companies enhance competitiveness and market presence by obtaining halal certification, using it as a marketing tool. Examples include Farmer Focus offering halal-certified chicken and Square-H Brands producing halal deli meats.
- **Regulatory Support:** Various authorities, like Halal Monitoring Authority (HMA) Canada and Halal Food Standards Alliance of America (HFSAA), provide halal certification, ensuring adherence to halal standards and boosting consumer confidence.



What Can We Test For?

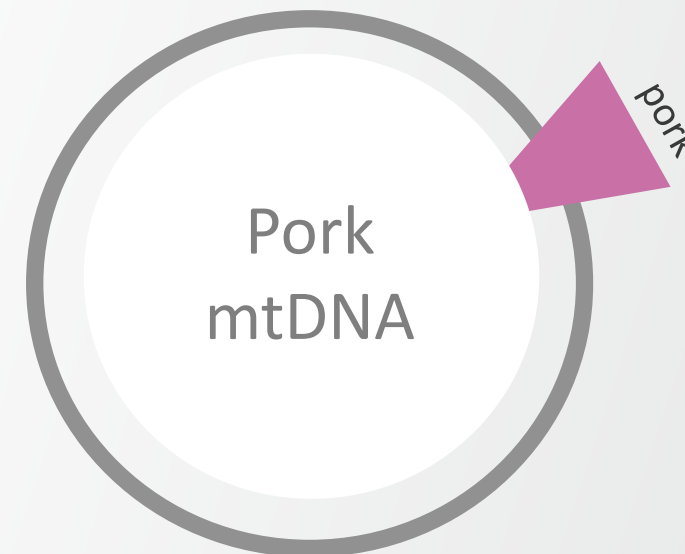


- There are religious (ceremonial) as well as practical elements to the definition.
- To date, there is no laboratory test on the market that can determine the way in which an animal is slaughtered.
- In terms of scientific testing, we have to define Halal foods as being **free from non-permitted ingredients**
- Species testing (pork) is obviously paramount in this market.
- **Basically, this refers to adulteration; either by accidental cross-contamination or adulteration for economic gain.**

The Thermo Scientific™ RapidFinder™ Halal ID Kit

Detection of Pork and Wild Boar

- Targets a highly specific mitochondrial region from gene 16s common to
 - Pork
 - Wild boar
- Presence / Absence result



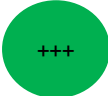




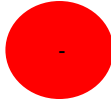
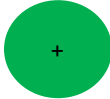



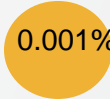
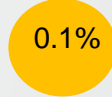
- To Quantify: Use in combination with RapidFinder Quant MultiMeat Set for Qualitative result
- Limit of detection < 0.0005%

The Thermo Scientific™ RapidFinder™ Halal ID Kit

- Order code: A47086
- Qualitative analysis to detect Pork and Wild Boar DNA
- **Limit of detection: 0.0005%** (compared to pork ID kit LOD 0.01%)
- Detection of **highly specific** mitochondrial region from gene 16s common to all pork and wild boar
- Contains 0.1% pork positive control
- Internal positive control **avoids false negatives due to PCR inhibitors**
- **Can be used in conjunction with the Rapid Finder Quant Multi-Meat kit for quantification**



Halal Competitor Kits

Assay name	RapidFinder Halal ID Kit			
Company	Thermo Fisher Scientific			
Technology	qPCR	qPCR	qPCR	qPCR
Detects	Pig and Wild Boar	Pig	Pig and Wild boar	Pig and Horse/Donkey
Food Integrity portfolio				
Microbiology portfolio				
Sensitivity				

RapidFinder Halal kit has the lowest limit of detection 0.0005% of pork DNA

What is Vegan?

- A vegan diet contains only plants such as vegetables, grains, nuts and fruits and foods made from plants.
- Veganism cuts out every item of animal origin
 - Meat
 - Fish
 - Eggs
 - Dairy
 - Honey



Why Do We Care About Vegan Mislabelling?

Second Pret A Manger Customer Dies from Allergic Reaction to Mislabeled Ingredient

The unidentified customer died after eating a sandwich with an improperly labeled dairy ingredient sold in the UK.

By **Maure Hohman** October 08, 2018 01:18 PM



The Vegan Society
One world. Many lives. Our choice.

Product Recall Alert

Thursday, 22 February, 2018

The FSA has issued a recall alert relating to vegan coconut yoghurts produced by CO YO. CO YO has investigated the source of the contamination and has found that the traces of dairy originated from a third party supplier with whom CO YO has now terminated its relationship.

CO YO recalls dairy free coconut milk yogurt products because of...

- Allergies
- Health risk
- Customer preference
- Personal dietary requirements
- Ethical issues
 - ✓ Sustainability
 - ✓ Environmental concerns
 - ✓ Animal welfare

Vegan food firm backed by Nigella Lawson ordered to recall 'dairy free' yoghurt that actually contains milk



Vegan doesn't always mean animal-free, says FSAI

The FSAI has issued an allergen warning due to the possibility of animal ingredients in vegan declared foods.

Vegan food warning as Iceland recalls 'milk-free' dessert that contains milk

The packaging is incorrect and people with allergies and on a plant-based diet need to be aware

By **Isaac Ashe** Deputy Digital Publishing Editor
19:40, 24 JAN 2020

Alerts / Alerts / Sainsbury's recalls Vegan Deli-Style Coleslaw and Vegan Potato Salad because they may...

ALLERGY ALERT

Sainsbury's recalls Vegan Deli-Style Coleslaw and Vegan Potato Salad because they may contain egg

13 December 2019

Sainsbury's is recalling by Sainsbury's Vegan Deli-Style Coleslaw and Vegan Potato Salad because they may contain egg which is not mentioned on the label. This means the products are a possible health risk for anyone with an allergy or intolerance to egg.

URGENT RECALL Iceland recalls 'No Cheese' pizzas, pasties and macaroni because they may contain milk

Helen Knagman, Digital Deputy Consumer Editor
1 Feb 2020, 12:34 | Updated: 1 Feb 2020, 12:51



The Food Safety Authority of Ireland (FSAI) has issued a public warning that vegan food may contain animal ingredients.

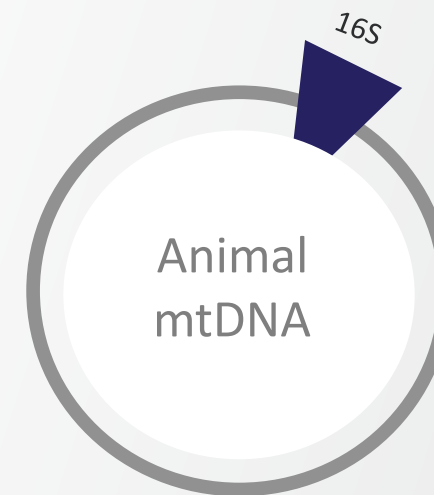
Many consumers assume that because a food is labelled as 'vegan' it will contain no ingredients of animal origin. In a bid to put consumers at ease, the FSAI has announced that it will issue a public warning...



The Thermo Scientific™ RapidFinder™ Vegan ID Kit

Detection of All Animal DNA

- Targets a highly conserved mitochondrial region from gene 16S
- Detects any animal origin DNA (including dairy, egg, fish, poultry). The only kit that is detecting all required DNA species at the same time



- Presence / Absence result
- Limit of detection < 0.01%



Thermo Scientific RapidFinder Vegan ID Kit

- Order code: A24412
- Qualitative analysis to detect all **animal derived DNA**
- Limit of detection: 0.01%
- Targets **any animal DNA** on a highly conserved mitochondrial region from gene 16s
- Contains 0.1% animal positive control
- Internal positive control avoids false negatives due to PCR inhibitors

* Sample must contain animal DNA



Competitive Landscape – Ethical Claims

Assay name	RapidFinder™ Vegan ID Kit				
Company	Thermo Fisher Scientific				
Technology	qPCR	qPCR	qPCR	qPCR	gPCR
Detects	Animal DNA	Animal DNA	Animal DNA	Pork, Beef, Horse, Donkey, Zebra (Multiplex) Chicken, Poultry (Aves), Turkey	All animals and birds
Food Integrity portfolio					
Strengths	Detects all animal origin DNA (all species inc Fish and bird) from a highly conserved mitochondrial region from gene 16s		Uses a mitochondrial target		
Weaknesses		Designed to be used with other animal tracker kits. No Fish DNA detection	No Fish DNA detection	Customer needs to use 2 kits to cover all possible species. No Fish detection	Does not detect fish DNA
Sensitivity	 <0.01%	 10 copies	 <100 copies	 <0.001%	 <0.01%

Rapid Finder Vegan kit is the only kit that detects also Fish DNA

Thermo Scientific SureTect PCR System Visibly simple food pathogen testing

Itziar Olea

Field Application Scientist Spain & Portugal

 The world leader in serving science



Product	New Format Sku	Existing Sku*
SureTect Salmonella species Assay	A56841	PT0100A
SureTect Listeria species Assay	A56842	PT0200A
SureTect L. monocytogenes Assay	A56843	PT0300A
SureTect Escherichia coli O157:H7 Assay	A56844	PT0400A
SureTect Cronobacter species assay	A56845	PT1060A
SureTect Escherichia coli O157:H7 and STEC Screening PCR Assay	A56838	A44254
SureTect Escherichia coli STEC Identification PCR Assay	A56840	A45330
SureTect Campylobacter jejuni, C. coli and C. lari PCR Assay	A56835	A44251
SureTect Vibrio cholerae, V. parahaemolyticus & V. vulnificus PCR Assay	A56837	A44253
SureTect Staphylococcus aureus PCR Assay	A56839	A44255
RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit	A56846	A33227
RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex Flex Kit	A56847	A33227KF



SureTect PCR Assay workflow



Enrichment



Using stepper pipette, add 10 μ L of Proteinase K Reagent to Lysis Tubes



Add 10 μ L of sample enrichment



10 minutes at 37°C then 5 minutes at 95°C



Multi-channel pipette



Transfer 20 μ L of DNA lysate to PCR tube



Vortex for 10 seconds
Flick to remove droplets



Run PCR

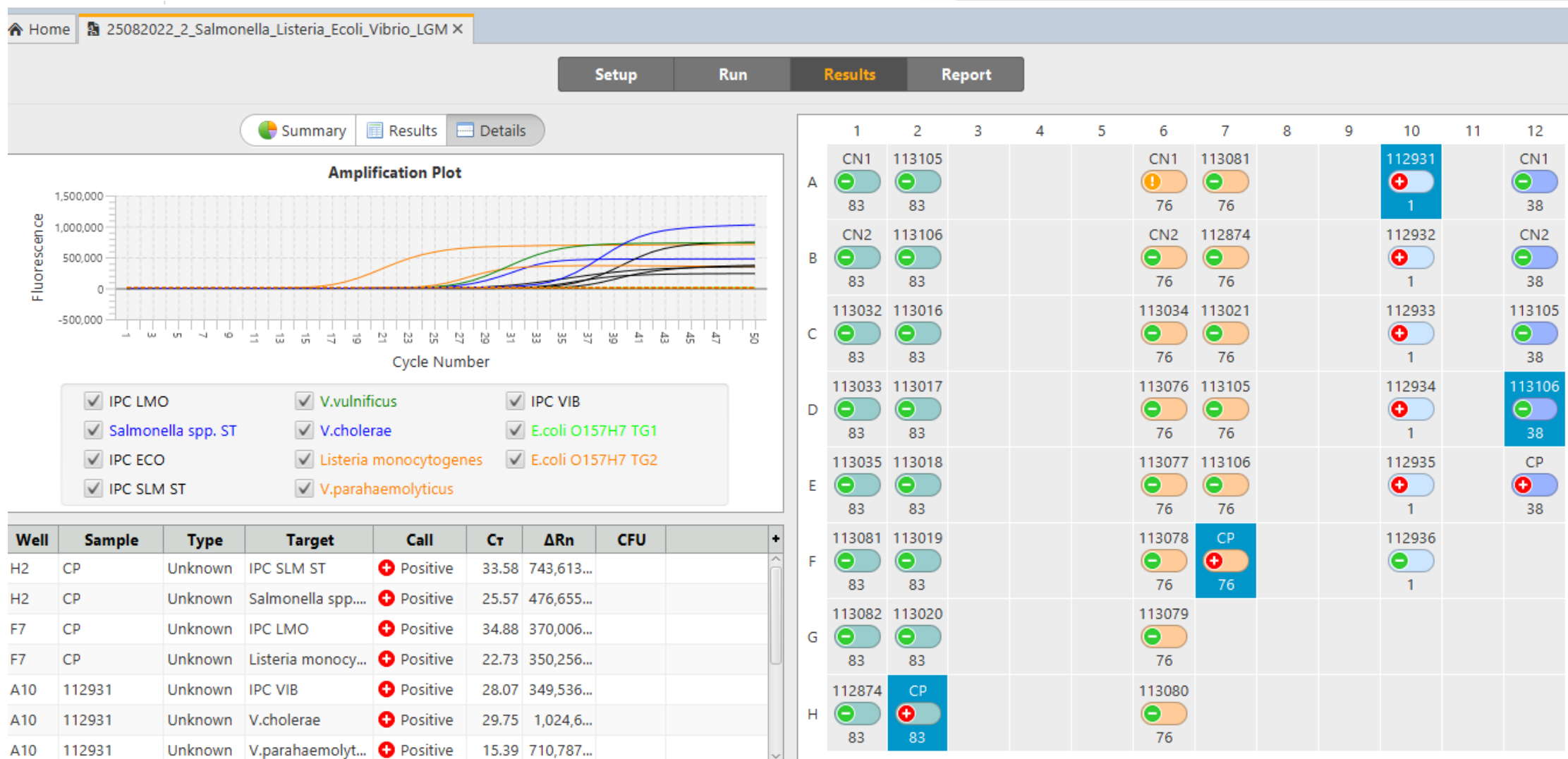
Pierceable seals for Lysis Tubes



Increased convenience and Efficiency





- Reduce handling steps with pierceable seals
- Single step for sealing Lysis Tubes
- Remove lysate aliquot with no need for decapping





SureTect Food Safety PCR System instrumentation






Applied Biosystems™ SimpliAmp™ Thermal Cycler

-  **Intuitive and easy interface**
 - Large, easy-to-use color touchscreen for easy programming and quick status checks (program once only for SureTect PCR Assay sample preparation)
-  **Flexible and open system**
 - Applied Biosystems™ VeriFlex™ Block provides three independent temperature zones for PCR optimization
-  **Cloud-enabled**
 - Conveniently access your instrument anytime, anywhere with the Connect Platform
-  **Maximize bench space**
 - Compact design helps save valuable bench space



SureTect Food Safety PCR System instrumentation

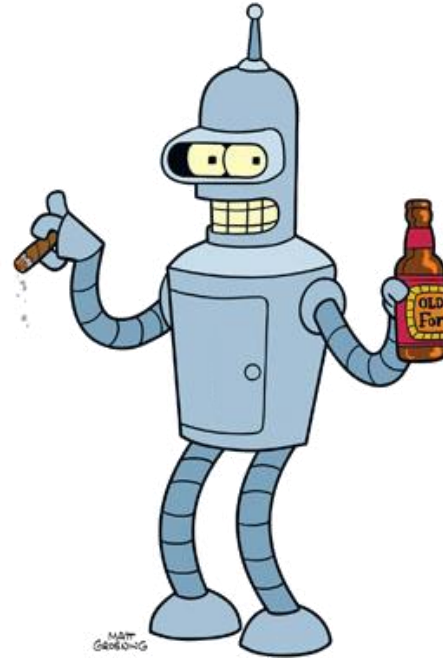
Applied Biosystems™ QuantStudio™ 5 Food Safety PCR System

-  **Intuitive and easy** to use for all levels of experience
 - Touchscreen usability, allowing you to stay connected to your data easily
-  **Multiplex with ease**—up to six excitation and six emission filters
 - 21 different color combinations, allowing a broad range of detection chemistries and maximum multiplexing
-  **Get up and running quickly**—factory-calibrated for accuracy, quick installation, and immediate use
 - Preoptimized protocol templates help minimize training for new users
-  **Maximize benchtop space**—compact instrument can be configured as a stand-alone or with a computer
-  **Open instrument**—suitable for all our food safety, authenticity, and quality PCR tests.
 - Cloud-enabled, offering the potential for data sharing, analysis and trending
 - Capacity for processing several hundred samples a day



What to achieve:

- Less handling time
- Less time-to-result
- More precision
- Increased process safety



What it should NOT be:

- Large
- Slow
- Complicated
- Expensive
- Time consuming

What it should be:

- Small foot print
- Easy to use
- Flexible
- Reliable
- Complete
- Fast



Automated SureTect Workflow!



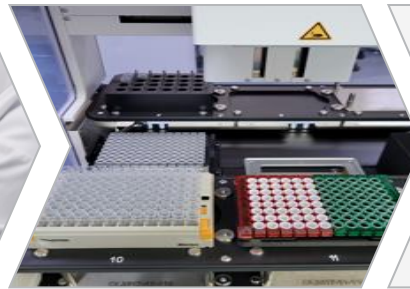
SureTect Automation Workflow steps



Enrichment



Add sample enrichment to sample tube



Load sample tubes, pipette tips, and reagents



Automated sample lysis & lysis and PCR setup - 40 min for 96 samples



Remove PCR tubes, seal and vortex for 10 seconds and flick to remove droplets



Run PCR ~ 80 mins for 96 samples

Only 5 minutes hands-on time (27 minutes for manual workflow) to process 96 samples

Just 1 manual pipetting step across the automation workflow

Test up to 96 samples or 6 assays in a single run

Pre-programmed runs for quick setup

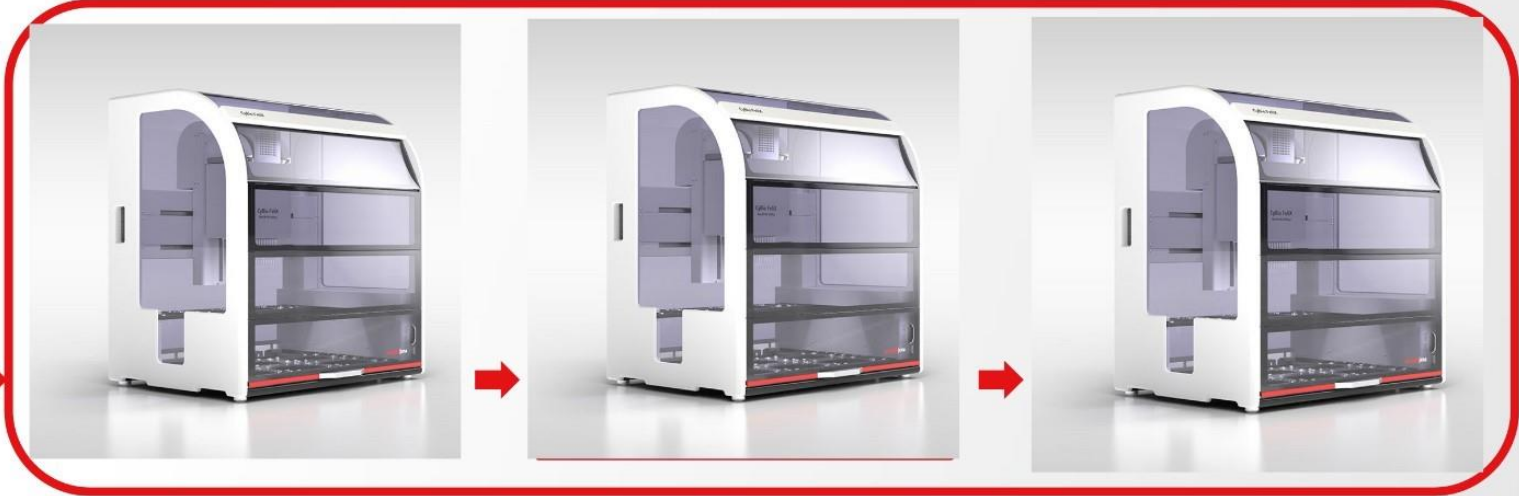
SureTect workflow: Manual to Automation



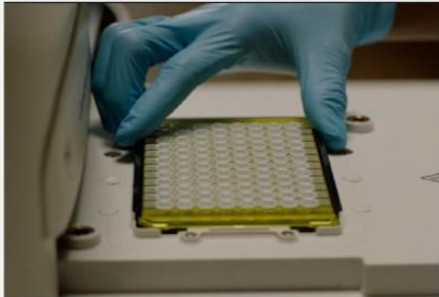
Separate desired number of lysis tubes



Remove seal from LysisTubes



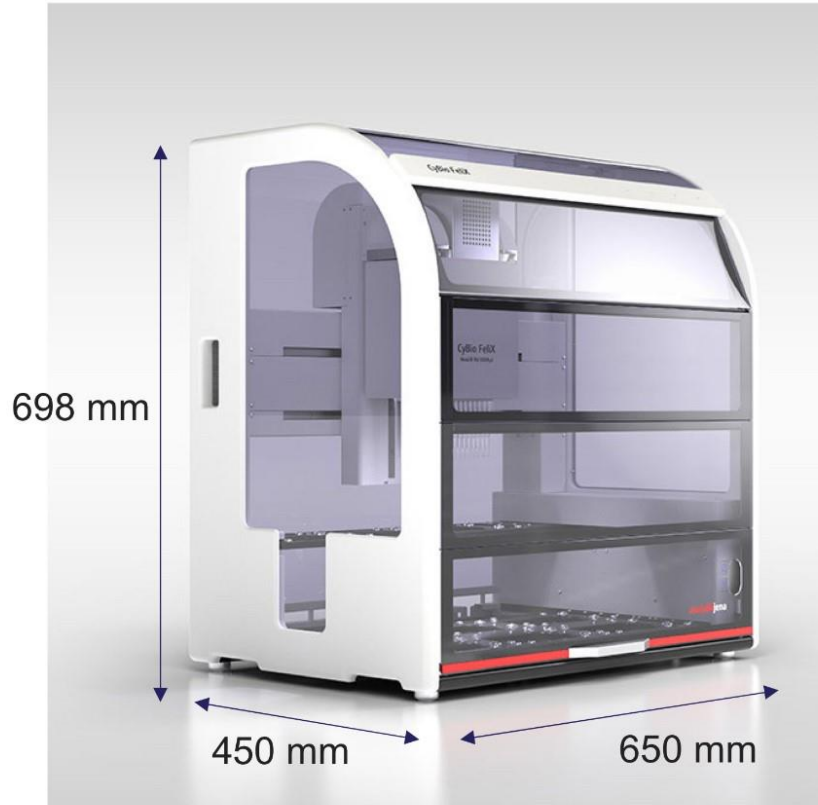
Separate and open desired number of PCR tubes



Vortex and Flick 10 seconds

Load into QuantStudio 5, run PCR & Review results

CyBio FeliX Instrument



✓ FlexPack

✓ UV



	Manual workflow	Automated Head R 96 workflow
Run time	42 min	39 min
Hands-On time	27 min	4-5 minutes



What is GMO?

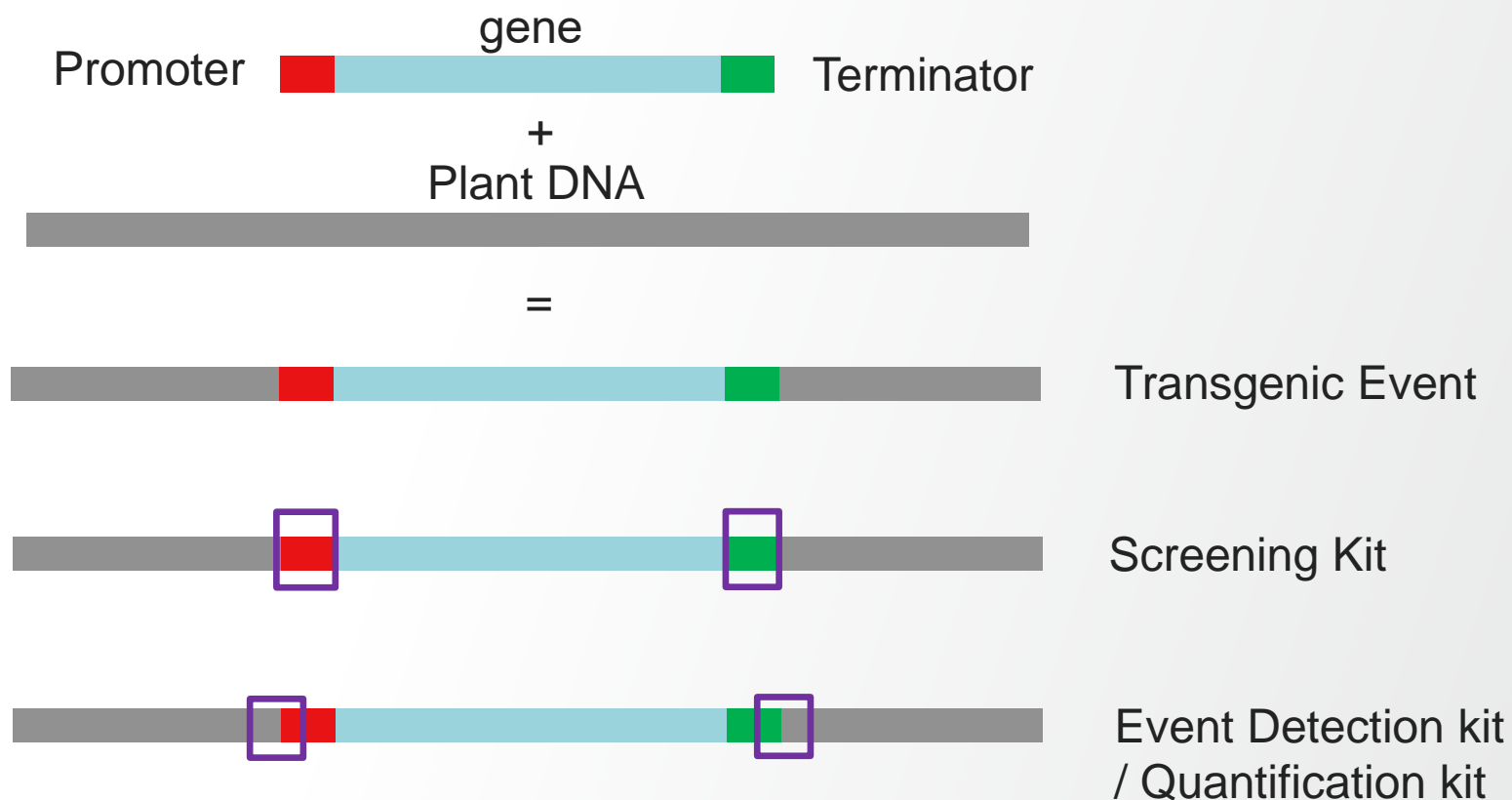
Genetically – Modified Organisms

- A genetically modified organism is one in which its natural genetic material (genome) has been modified through specific genetic manipulation techniques. These modifications confer:
 - Insect resistance (corn, potato, cotton)
 - Herbicide tolerance (soybeans, corn, rapeseed and cotton)
 - Virus resistance (potato and papaya)
 - Delayed ripening (tomato)
 - Alternation of colour/ nutritional characteristics (potato, rice)
- A transgenic Event: The term "**transgenic event**" is used to differentiate genetically modified crop varieties.
 - A total of 614 Events are authorized Globally
 - 163 Events are authorized in EU
 - 2 new events were authorized in the last month in EU



How is a GMO crop made?

And how qPCR works





BIOTECH SOYBEANS

FIRST COMMERCIAL PLANTING IN 1996

95.9 MILLION HECTARES
TOTAL AREA IN 2018

APPROVED FOR IMPORT IN
18 COUNTRIES

PLANTED BY FARMERS IN
9 COUNTRIES

USA BRAZIL ARGENTINA
PARAGUAY CANADA URUGUAY
BOLIVIA SOUTH AFRICA CHILE

38 APPROVED EVENTS IN
31 COUNTRIES

SOYBEANS **50%** OF THE WORLD'S
ACCOUNT FOR BIOTECH CROP AREA

USA IS THE WORLD'S TOP PRODUCER
OF SOYBEANS
BRAZIL IS THE TOP EXPORTER
OF SOYBEANS IN THE WORLD

78%
OF SOYBEAN GLOBAL
AREA OF 123.5 MILLION
HECTARES IN 2018
IS BIOTECH

For more, download: bit.ly/2018Soybeans

BIOTECH MAIZE

FIRST COMMERCIAL PLANTING IN 1996

58.9 MILLION HECTARES
TOTAL AREA IN 2018

APPROVED FOR IMPORT IN
15 COUNTRIES

PLANTED BY FARMERS IN
14 COUNTRIES

USA BRAZIL ARGENTINA CANADA PARAGUAY
SOUTH AFRICA URUGUAY PHILIPPINES SPAIN COLOMBIA
VIETNAM HONDURAS CHILE PORTUGAL

137 APPROVED EVENTS IN
35 COUNTRIES

MAIZE EVENT **NK603** RECEIVED **61** APPROVALS FROM
28 COUNTRIES

30%
OF MAIZE GLOBAL
AREA OF 197.2 MILLION
HECTARES IN 2018
IS BIOTECH

For more, download: bit.ly/2018Maize

BIOTECH COTTON

FIRST COMMERCIAL PLANTING IN 1996

24.9 MILLION HECTARES
TOTAL AREA IN 2018

APPROVED FOR IMPORT IN
8 COUNTRIES

PLANTED BY FARMERS IN
15 COUNTRIES

USA BRAZIL ARGENTINA INDIA PARAGUAY
CHINA PAKISTAN SOUTH AFRICA AUSTRALIA MYANMAR
SUDAN MEXICO COLOMBIA COSTA RICA ESWATINI

63 APPROVED EVENTS IN
27 COUNTRIES

INDIA IS TOP COTTON PRODUCER
IN THE WORLD

7.5 MILLION FARMERS
AND THEIR FAMILIES
IN INDIA HAVE ENJOYED THE
BENEFITS OF PLANTING BT COTTON

76%
OF COTTON GLOBAL
AREA OF 32.9 MILLION
HECTARES IN 2018
IS BIOTECH

For more, download: bit.ly/2018Cotton

BIOTECH CANOLA

FIRST COMMERCIAL PLANTING IN 1996

10.1 MILLION HECTARES
TOTAL AREA IN 2018

APPROVED FOR IMPORT IN
10 COUNTRIES

PLANTED BY FARMERS IN
4 COUNTRIES

USA CANADA AUSTRALIA CHILE

37 APPROVED EVENTS IN
15 COUNTRIES

95% BIOTECH CANOLA'S
ADOPTION RATE IN CANADA

CANADA PLANTED 8.7 MILLION HECTARES
BIOTECH CANOLA IN 2018

MOST OF BIOTECH CANOLA
PLANTED IN CANADA ARE **HERBICIDE TOLERANT**

CHILE GROWS BIOTECH CANOLA
FOR SEED EXPORT

29%
OF CANOLA GLOBAL
AREA OF 34.7 MILLION
HECTARES IN 2018
IS BIOTECH

For more, download: bit.ly/2018Canola

BIOTECH ALFALFA

FIRST COMMERCIAL PLANTING IN 2006

1.3 MILLION HECTARES
TOTAL AREA IN 2018

APPROVED FOR IMPORT IN
5 COUNTRIES

PLANTED BY FARMERS IN
2 COUNTRIES

USA CANADA

5 APPROVED EVENTS IN
10 COUNTRIES

CANADA PLANTED **HARVXTRA™**
ALFALFA
USA PLANTED **RR® & HARVXTRA™**
ALFALFA

HARVXTRA™ ALFALFA
WAS FIRST PLANTED IN 2016

HIGH DEMAND FROM FARMERS

- CONTAINS LESS LIGNIN
- HIGHER DIGESTIBILITY
- OFFERS 15-20% YIELD INCREASE

BIOTECH ALFALFA ADOPTION RATES IN THE USA
AND CANADA IS LIKELY TO INCREASE AS MORE
AND MORE FARMERS REALIZE THE BENEFITS OF THE
TECHNOLOGY IN LIVESTOCK PRODUCTION AND FARM
MANAGEMENT.

For more, download: bit.ly/2018Alfalfa



TOP 5 BIOTECH CROPS IN THE WORLD

WWW.ISAAA.ORG

AN ISAAA INFOGRAPHIC BY CLEMENT DIONGLAY

SOURCES: ISAAA Brief 54 (bit.ly/ISAAA54)
ISAAA GM Approval Databases (bit.ly/GMApprovalDatabase)
ISAAA Pocket K No. 2 (bit.ly/PKNo2)

NOTE: In these ISAAA resources, the European Union (EU = 28 countries) is counted as one (1) country.

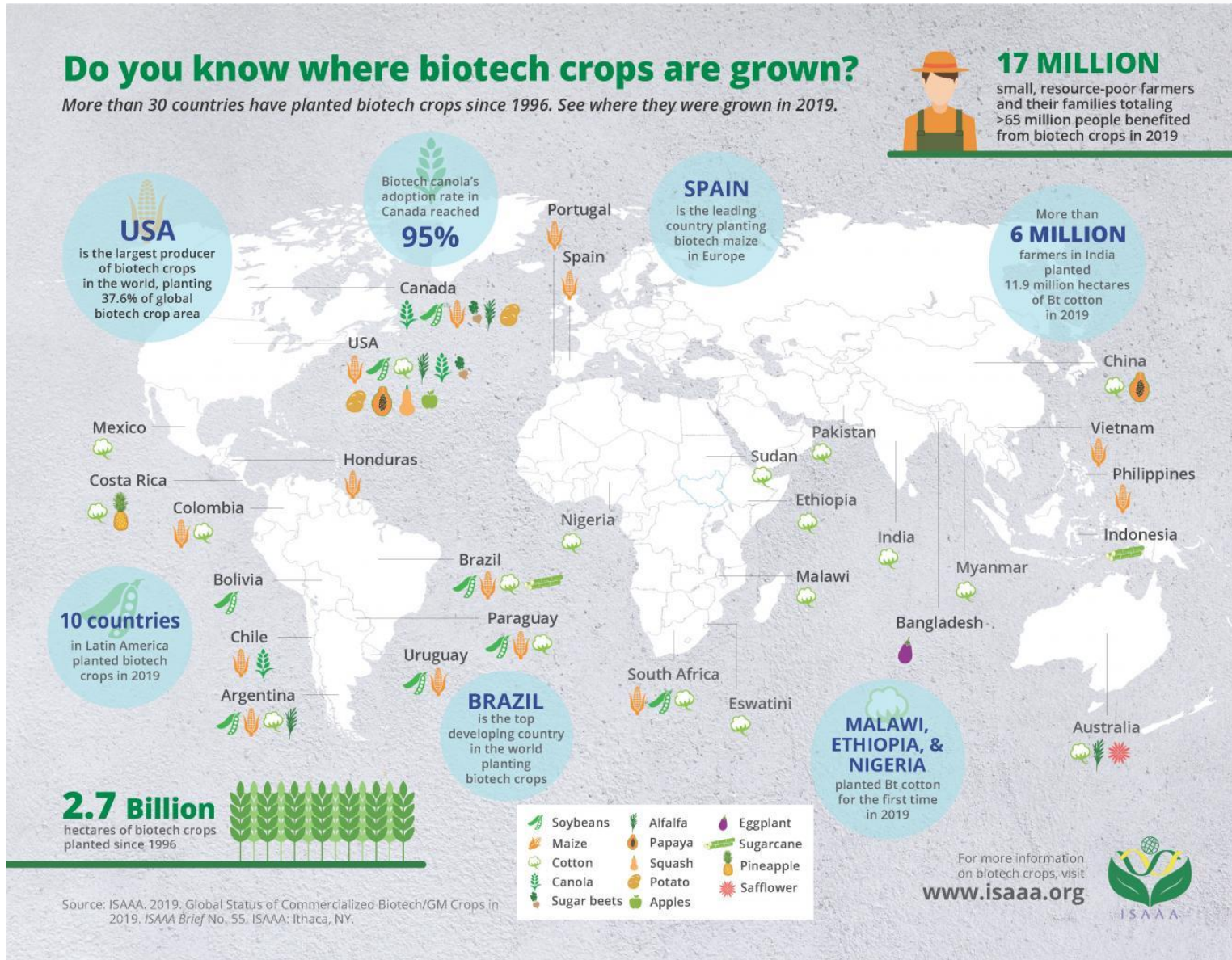
www.facebook.com/isaaa/

www.instagram.com/isaaa_org/

www.twitter.com/isaaa_org

JUNE 2020

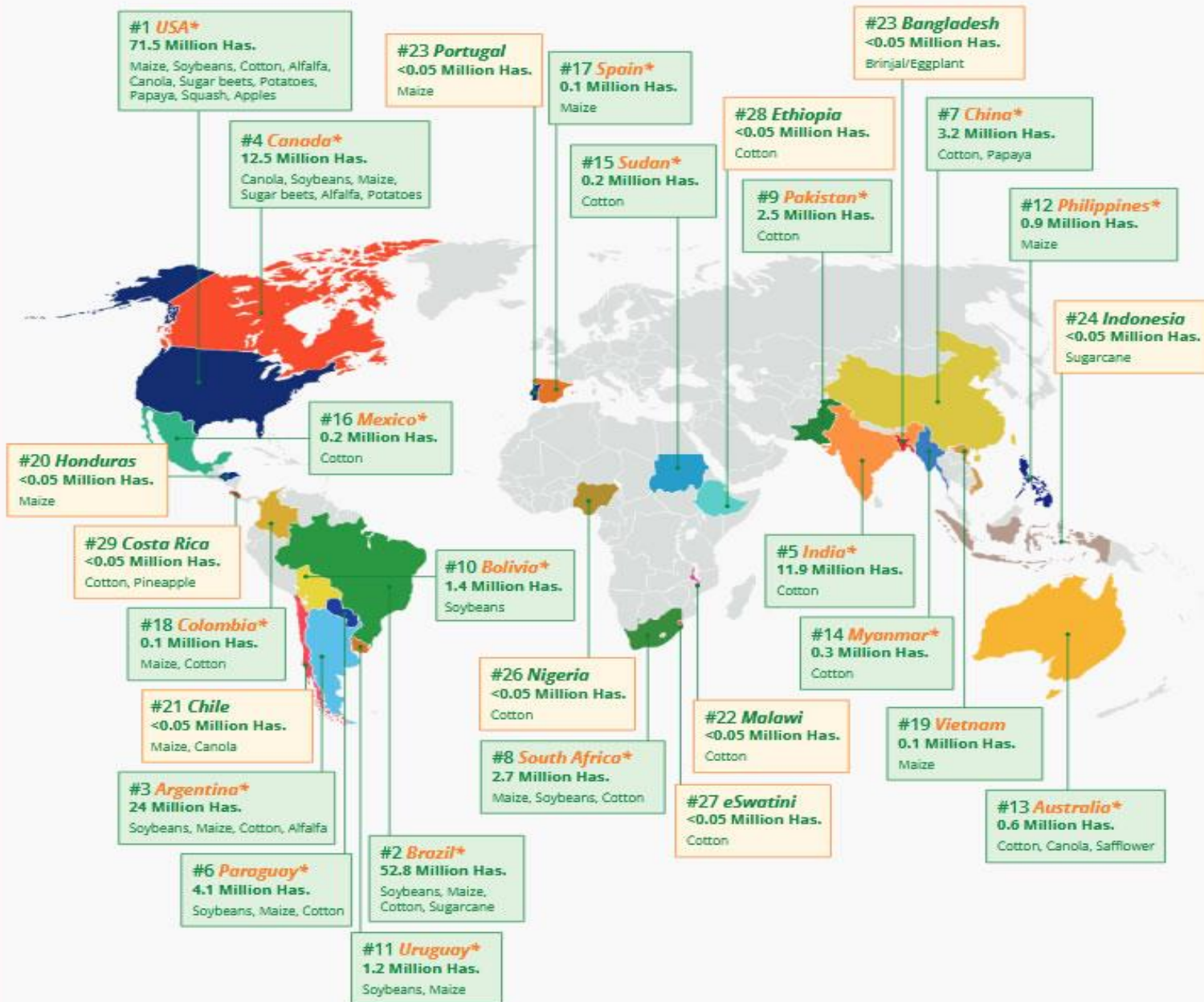
GMO crops are found globally



USA is the largest producer of GMO crops

2.7 Billion Hectares of biotech crops planted

Only one GMO has been approved for cultivation in the EU so far. Maize MON 810 was authorised for cultivation in 1998

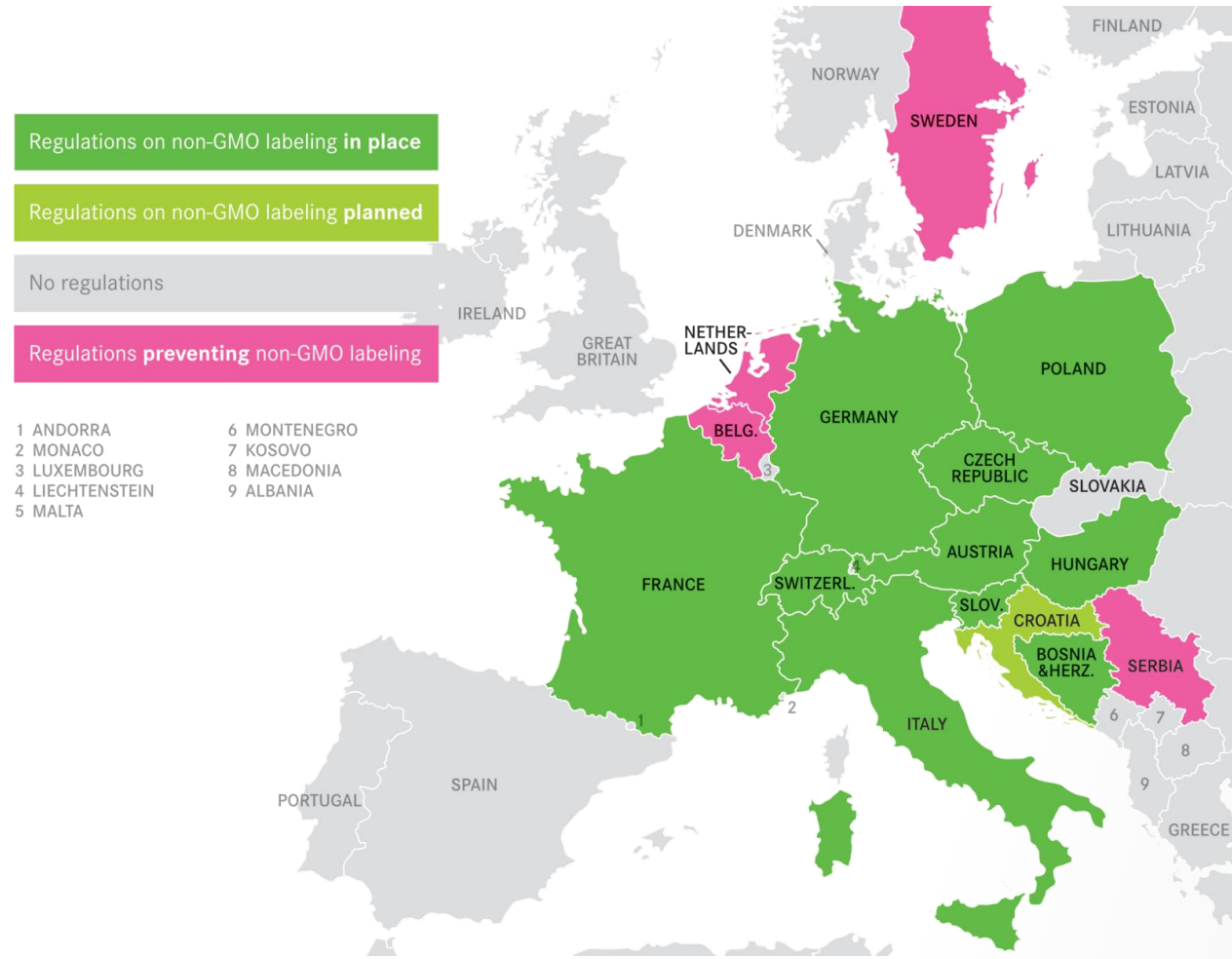


 *19 biotech mega-countries growing 50,000 hectares, or more, of biotech crops.

- A total of 72 countries approved transgenic crops: 29 countries planted and 43 countries imported.
- Most GMO raw materials (i.e. seeds) are produced and imported from America, where the evaluation of novel GMO events is an active process.
- In 2019, the area corresponding to transgenic crops reached 12% of the total cultivated land

GMO status in EU

Each region has its own legislations



Non-GMO Labelling

Any non-GMO labelling must comply with strict requirements. The entire food and feed production process is checked to ensure the absence of GMOs – from seed to cultivation on the fields to processing and all the way to packaging, including the correct use of the non-GMO label. External monitoring and certification bodies, as well as national food and feed control authorities, ensure that all labelled non-GMO products fully comply with the requirements related to non-use of GMOs, from seed to final product.

European Regulations

The European Union (EU) has established a comprehensive legal framework for the regulation of genetically modified organisms (GMOs). The primary regulations include:

- **Directive 2001/18/EC:** This directive concerns the deliberate release of GMOs into the environment. It requires a thorough environmental risk assessment before any GMO can be released or marketed. The directive also includes provisions for public consultation and labeling.
- **Regulation (EC) No 1829/2003:** This regulation covers GMOs intended for food and feed. It mandates a stringent authorization process, including a risk assessment by the European Food Safety Authority (EFSA), before any GMO can be placed on the market. It also requires labeling of all food and feed products containing GMOs above a certain threshold.
- **Regulation (EC) No 1830/2003:** This regulation ensures traceability and labeling of GMOs and products produced from GMOs throughout the supply chain. It aims to facilitate accurate labeling and monitoring of potential effects on health and the environment.
- **Regulation (EC) No 1946/2003:** This regulation implements the Cartagena Protocol on Biosafety, governing the transboundary movements of GMOs. It ensures that countries are informed about GMOs that may be imported into their territory, allowing them to make informed decisions.
- **Regulation (EU) No 503/2013:** This regulation specifies the data requirements for the risk assessment of genetically modified food and feed. It provides detailed guidelines on the types of studies and data needed to evaluate the safety of GMOs.
- **Regulation (EC) No 834/2007:** This regulation relates to organic production and labeling of organic products, explicitly prohibiting the use of GMOs in organic farming.



PLANTS

GMO Legislation in the European Community

Threshold for accidental presence of GMOs

- The accidental presence of GMOs in traditional crops is accepted. This contamination can occur during cultivation, harvesting, transportation or treatment.
- Foods with traces of GMOs (unintentional and technically unavoidable presence) are exempt from the labeling obligation if said presence does not exceed the threshold of **0.9% in each ingredient**.
- The operator must demonstrate to the authorities the accidental or technically unavoidable nature of the presence of GMOs.



GMO Labelling

Country	Mandatory vs. voluntary labelling	Product vs. process labelling	Threshold level (%)
European Union	Mandatory	Process	0.9
China	Mandatory	Process	0
Brazil	Mandatory	Process	1
Australia/ New Zealand	Mandatory	Product	1
Japan	Mandatory	Product	5
Korea	Mandatory	Product	3
Canada	Voluntary	Product	5
USA	Voluntary	Product	N/A



Testing Requirements – who, what and why

Varies according to the region

GMO-free Countries

No GMOs allowed – any GMO containing food or feed is not accepted

- GMO screening is enough because if positive then the food or feed is banned from the market

GMO regulated countries

Specific GMO Events are allowed. GMO-containing food or feed are labelled

- GMO screening and if positive GMO Event identification and GMO quantification

GMO producing countries

Producers of GMO crops and exporters to other regions

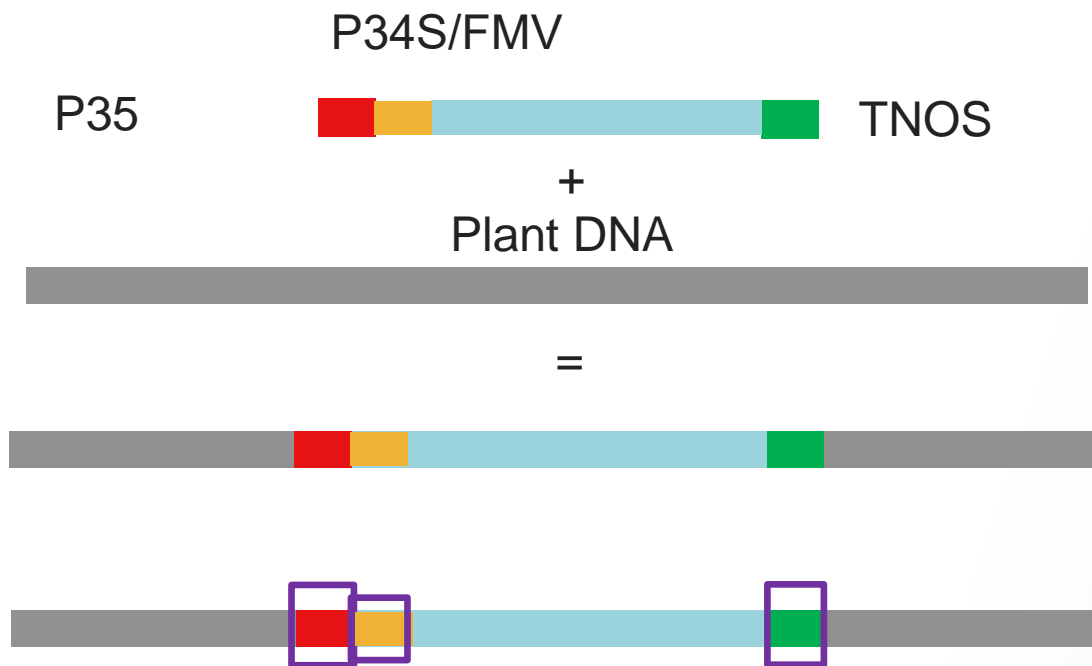
- GMO Event Identification to allow for exports in various regulated regions

GMO: what can we test?

- **Specific GMO Events:** specific genetic modifications or "events" in crops. For instance, they can detect the presence of specific transgenes such as MON810 (a genetically modified maize) or Bt11 (another type of genetically modified maize).
- **Promoter and Terminator Sequences:** Some kits are designed to detect common genetic elements used in GMOs, such as the Cauliflower Mosaic Virus 35S promoter (CaMV 35S) or the nopaline synthase (T-NOS) terminator. These elements are frequently used in GMO constructs and can indicate the presence of GMOs.
- **Screening for Multiple GMOs:** Comprehensive GMO qPCR kits can screen for multiple GMO events simultaneously. These multiplex kits are useful for regulatory compliance and routine monitoring, allowing the detection of various GM crops like soy, maize, cotton, and canola in a single test.
- **Quantification:** Beyond mere detection, qPCR kits can quantify the amount of GMO present in a sample. *This is particularly important for meeting labeling requirements, where the percentage of GMO content must be disclosed if it exceeds a certain threshold.*

The Thermo Scientific™ TaqMan™ GMO Screening Kit

3 duplex reactions in one Screening kit :



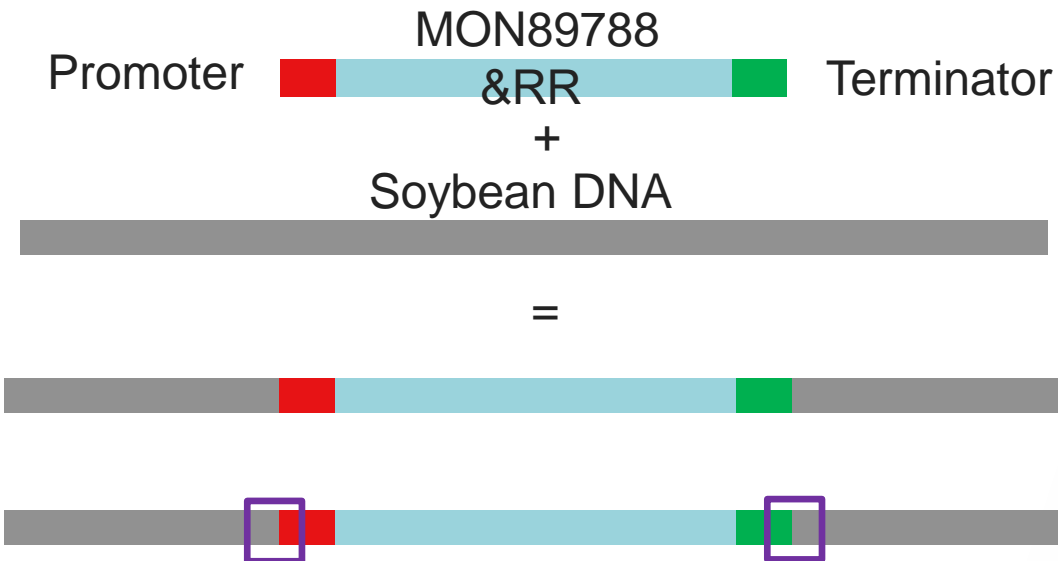
REACTIONS
1. P35S/CaMVcauliflower mosaic virus
2. TNOS/ <i>Agrobacteriumtumefaciens</i>
3. P34S/FMV figwort mosaic virus
4. Plant/IPC

- P35S is the promoter of CAMV
- TNOS is the terminator of Agro
- P34S/FMV is the promoter of FMV

These regulatory elements are used in most GMOs approved by the EU and are described in GMO databases worldwide. P35S and TNOS are traditionally analyzed to screen for transgenic material in foods. P34S is analyzed to identify the presence of:

- • MON89788 soybean
- • H7-1 sugar beet
- • GT73 rape
- • Other genetically modified crops that use this more recently adopted promoter element

The Thermo Scientific™ TaqMan® MON89788 & Roundup Ready soy event ID Kit



Reagents	Color	Amount	Storage
MON89788 & RR Master Mix	Yellow pad	360 µL	-20°C
General Master Mix	White pad	600 µL	4°C
Positive Control	Blue cap	60 µL	-20°C

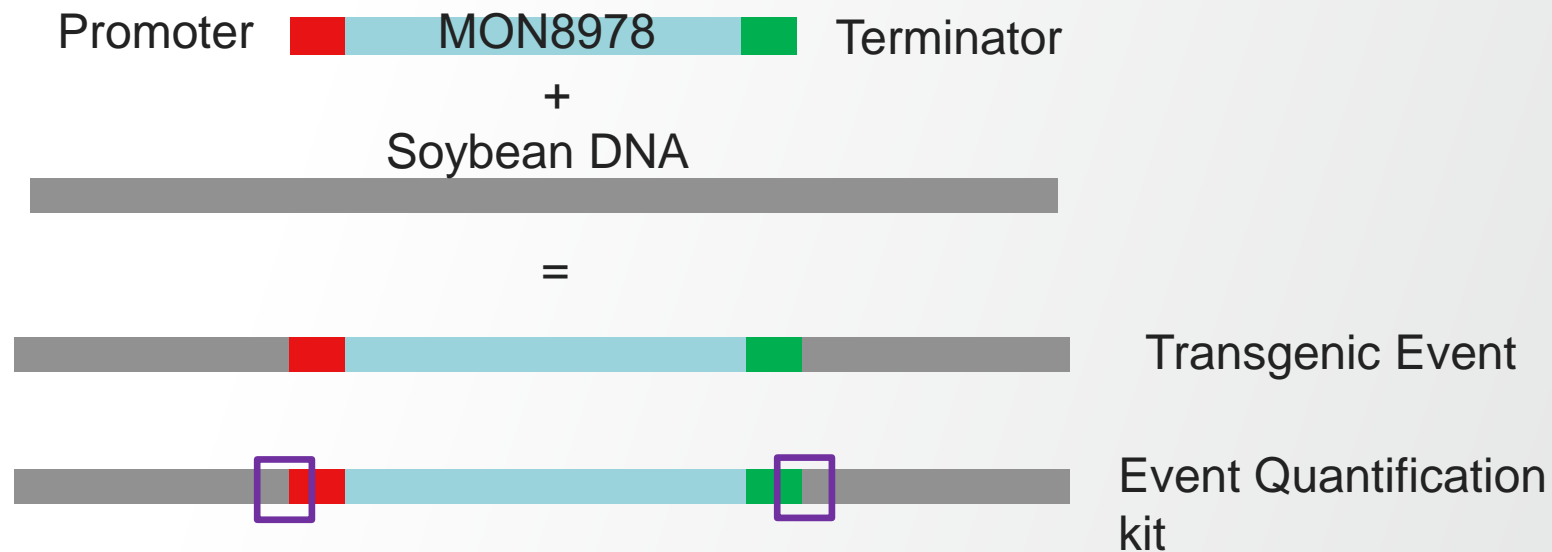
Transgenic Event

Event Detection kit

The Thermo Scientific™ TaqMan™ MON89788 and Roundup Ready™ Soya Event ID Kit enables real time PCR detection of MON89788 and Roundup Ready™ transgenic soybean DNA in a sample. The kit detects a percentage >0.01% of MON89788 and Roundup Ready™ transgenic soybean DNA. The kit is ISO 9001 and ISO 14001 compliant.

The Thermo Scientific™ TaqMan® MON89788 Quantification Kit

Reagents	Colour	Volume	Storage
MON89788 Master Mix	Blue pad	360 µL	-20°C
Soy Master Mix	Purple pad	360 µL	-20°C
General Master Mix	White pad	2 x 600 µL	4°C
MON89788 Standard	Brown cap	6 x 50 µL	-20°C



Two quantifications for each sample:

- endogenous gene: Gene present in the species to be analyzed. Maize or Soybeans
- Transgenic sequence: Promoter, terminator or specific sequence of each transgenic variety
- Comparison of the samples to standards of known GMO concentration or with a known number of DNA copies
- The sample must be interpolated between the standards used

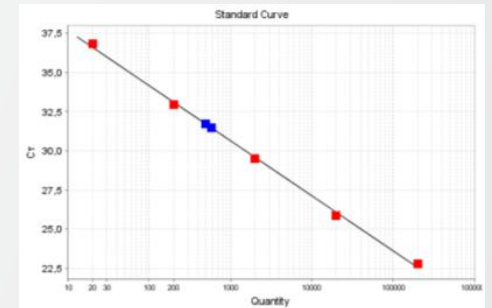
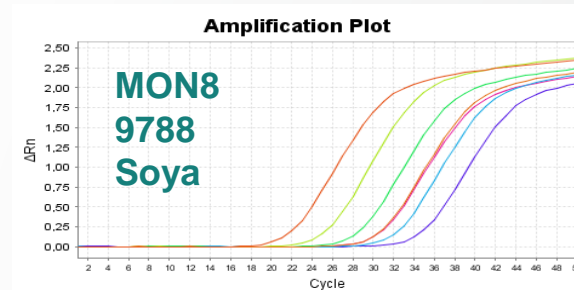
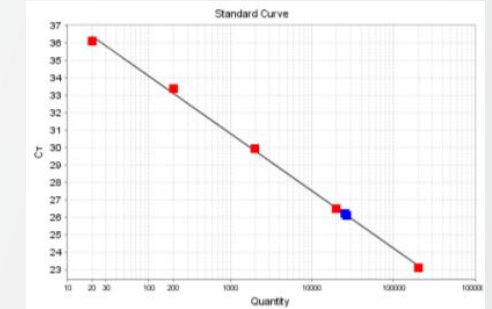
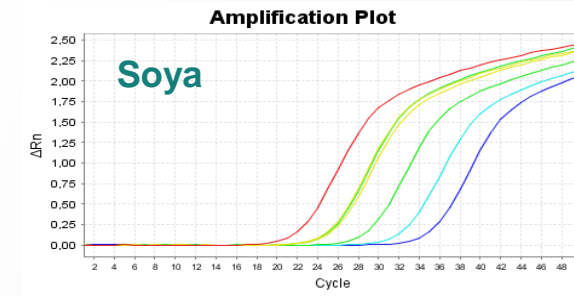


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The Thermo Scientific™ TaqMan® MON89788 Quantification Kit

More information

- The Thermo Scientific™ TaqMan™ MON89788 Quantification Kit enables **relative quantification of as little as 0.1% of MON89788 (Roundup Ready™ 2) transgenic soybeans** with respect to total soya in a sample.
- The kit is ISO 9001 compliant.
- The absolute limit of quantification is 20 copies of DNA, and the detection limit of the PCR technique is 5 copies each of MON89788 and soya DNA.



$$\%GMO = \frac{\text{Number of transgene copies} \times 100}{\text{Endogenous copy number}}$$



Example of Quantification for Labeling purposes

Remember the EU accepted limit for **each GMO ingredient** is 0.9%



Example:
Pizza prepared with soy flour (5% w/w)

0.2% RR soya
0.7% RR2 soya
0.8% GMO maize → LABEL GMO soya

0.7% RR soya
0.3% RR2 soya → >0.9% GMO soya
↓
Labeled as
GMO soya

0.7% RR2 soya → LABEL non- GMO
0.8% GMO maize

Who needs to test for GMO and why?

- **Food and Feed Testing:** to ensure compliance with labeling regulations, qPCR kits can test raw ingredients, processed foods, and animal feed for the presence and quantity of GMOs (screening kits)
- **Environmental Monitoring:** qPCR kits can also be used to monitor the presence of GMOs in the environment, such as in soil or water samples, to study the potential impact of GMOs on ecosystems.
- **Seed and Crop Testing:** Agricultural producers and seed companies use qPCR kits to test seeds and crops for GMO content, ensuring purity and compliance with non-GMO certification standards.



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TaqMan® GMO Screening Kit (IMEGEN) Targeting & Positioning

Target Customers

Contract labs

Producer labs:

- Ready to eat
- Chocolate
- Feed producers
- Government Labs



Positioning (for the GMO Screening Kit):

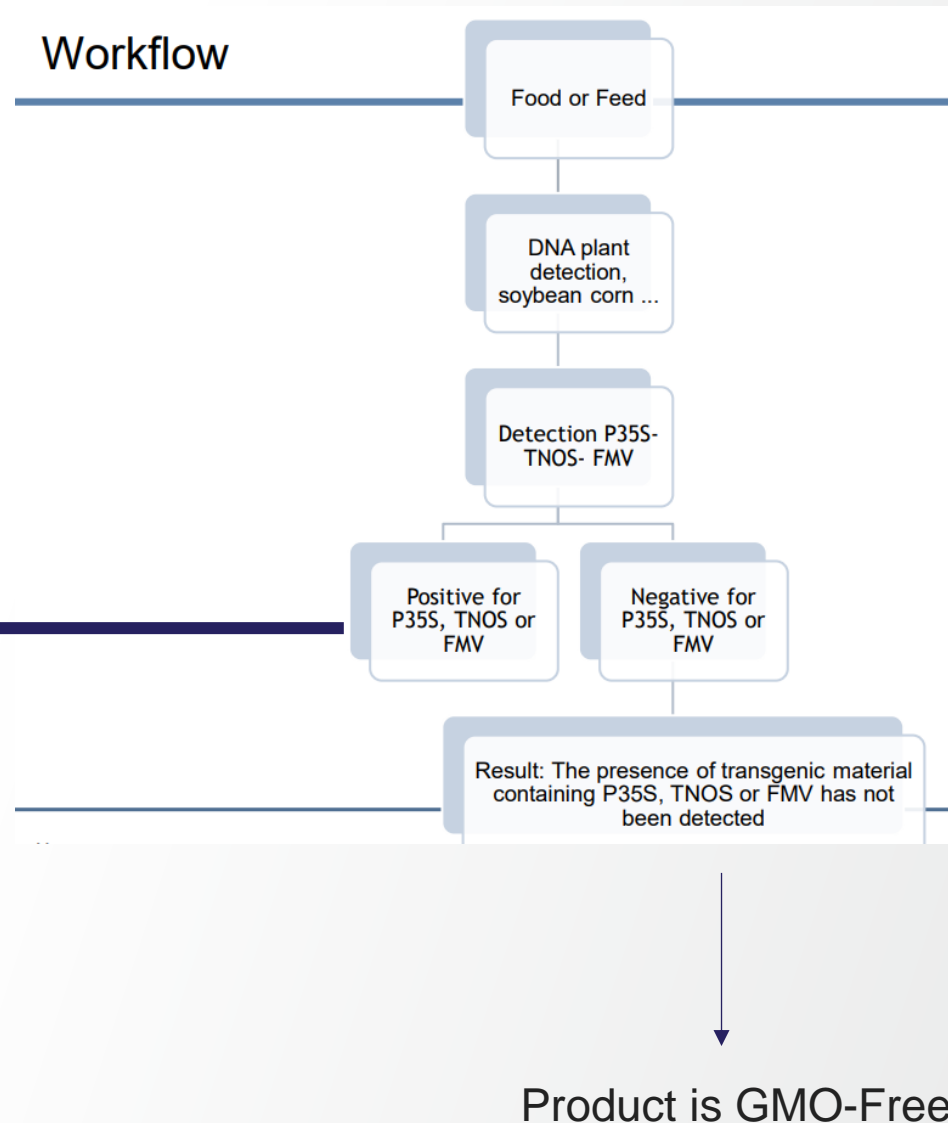
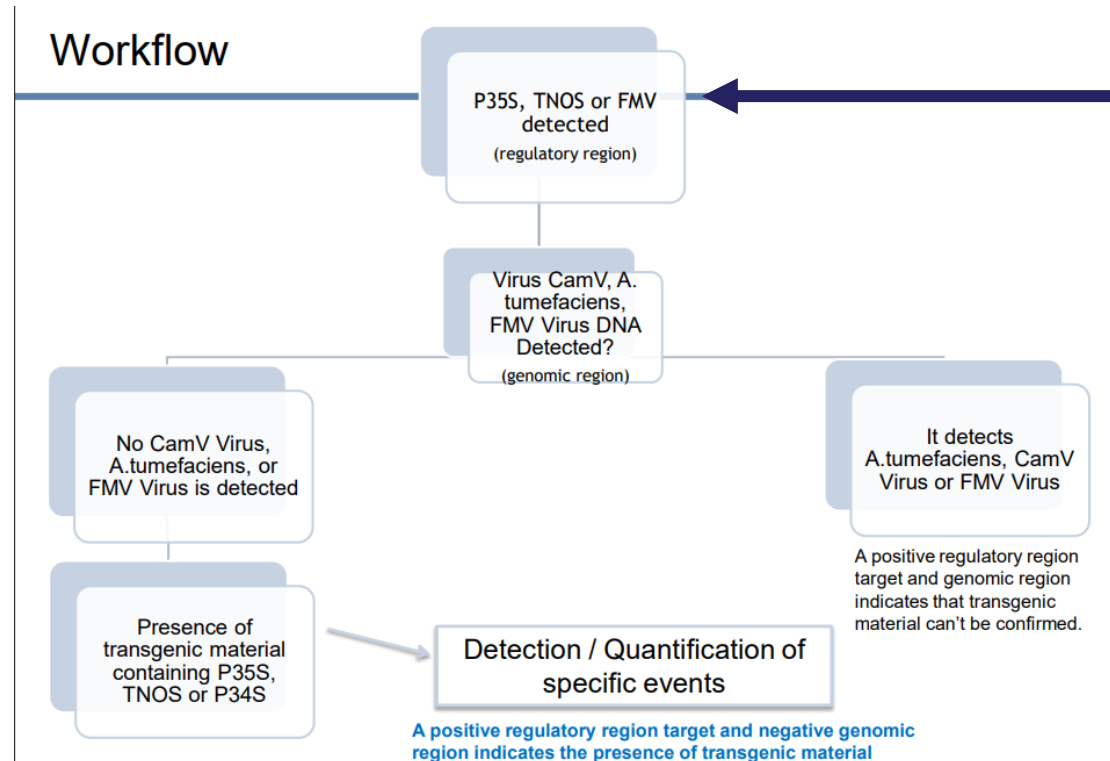
- A reliable method to accurately detect GMO contaminants in soy, maize, cotton seed, canola, and composite foods.
- Unlike other competitors we provide a method that
 - reduces sampling error by starting with up to 20 g sample
 - reduces false positives by including controls for naturally occurring plant viruses, and
 - enhances accuracy and reliability by including both reference gene and IPC controls

GMO Testing – The Prospective Customer: PRODUCERS

We can WIN with PRODUCERS because:

- **Consumer demand** is driving producers to offer non-GMO products
- **Conscientious** producers and **specialty** retailers target discerning consumers with greater options for non-GMO products.
- Non-GMO products = **premium** products which command a higher price but not necessarily higher cost.
- Even the big 5 producers – Campbell's (1st), ConAgra/DelMonte, General Mills, Mars, and Kellogg's are proactively labeling products made with GMO for **transparency**.
- Our GMO kits offer exceptional specificity and sensitivity.
- The customer base is **sizeable**: raw ingredients, feed, suppliers, processors, and beauty care are all offering non-GMO products

A customer's Workflow in GMO-regulated country







Product is GMO-Free

MBD offering

GMO Kits available

Name of the product	MBD SKU	intended USE	Limit of Detection	# samples per kit	Specificity / Sensitivity
TaqMan® GMO Screening Kit	4466334	Screening GMO	0.1% (w/w) of GMO plant species	48 reactions	100%/100%
TaqMan® MON89788 & Roundup Ready soy event ID Kit	A43720	Transgenic Event kits	0.01% (w/w) of MON89788 & RR DNA	48 reactions	100%/100%
TaqMan® MON89788 Quantification Kit	4466335	Transgenic Event Quantification kits	LOQrel; 0.1% (w/w)/ LOQabs; 20 total copies for Soya lectin and MON89788	48 reactions	100%/100%
TaqMan® Roundup Ready Alfalfa Quantification Kit	4327696	Transgenic Event Quantification kits	LOQrel:01,1 (w/w) / LOQabs: 20 total copies for each of the quantifiable systems	48 reactions	100%/100%
TaqMan® Roundup Ready Soya Quant.	4466335	Transgenic Event Quantification kits	LOQ: 20 copies of DNA /LOD: 3 DNA copies	48 reactions	100%/100%
TaqMan® TNOS Maize Quantification Kit	ESIG008	Transgenic Event Quantification kits	LOQ: 20 copies of DNA / Detection limit of the PCR technique (Maize system): 3 copies of DNA, Detection limit of the PCR technique (TNOS system): 5 copies of DNA	50 reactions	100%/100%
TaqMan™ GMO P35S Maize Quantification Kit	4481972	Transgenic Event Quantification kits	LOQ: 20 copies of DNA / Detection limit of the PCR technique (Maize system): 3 copies of DNA, Detection limit of the PCR technique (P35S Maize system): 3 copies of DNA	50 reactions	100%/100%

Competitive Landscape – GMO screening

Assay name	Taqman GMO Kits	SureFood® GMO kits	foodproof® GMO Screening	BF GMO kits
Company	Thermo Fisher Scientific	R-Biopharm	Hygiena	Gennaxon
Technology	qPCR multiplex	qPCR multiplex	qPCR multiplex	qPCR multiplex
Breadth of analysis	1 screening kit	2 screening kits	3 screening kits	5 multiscreen kits
Detects	<p>P35S TNOS P34S FMV</p> <p>IPC CAMV</p> <p>BAR PAT NPTII</p>	<p>P35S TNOS FMV IPC</p> <p>BAR PAT NPTII CPT2 CPT4 EPSPS</p> <p>CAMV</p> <p>BAR PAT CryiAb CPT2 CPT4 EPSPS</p> <p>P35S:BAR rice</p>	<p>P35S TNOS FMV</p> <p>BAR P35S - PAT TNOS - NPTII CPT2 CPT4 EPSPS</p> <p>P35S - NPTII</p> <p>P35S TNOS FMV IPC</p>	<p>P35S TNOS CAMV</p> <p>P35S TNOS P34S FMV</p> <p>CAMV IPC</p> <p>TNOS NOS Agrobact. FMV P35S</p> <p>P35S CAMV</p>
Strengths	Imegen has capabilities to develop new kits (technology is ready) upon market need (7-8 months). Imegen also has a lab that can run the analysis (as a service provider TBD)	Price competitive	Partially lyophilised reagents (easier workflow)	
Weaknesses	Missing some additional screening Genes Not detecting all available transgenic Events		No quantification kits	
Comp Matrix				

GMO kits – Value proposition

For	Food manufacturers, retailers and contract labs servicing food manufacturers
Who	want to ensure the absence of GMOs or quantify for Labelling purposes
Our	TaqMan® GMO Kits
Product Benefit	Offer sensitive and reliable detection of GMO Events using a simple, reproducible workflow
Customer Benefit	Enabling customers to verify their sourced products and ingredients quickly
Our	Solution offers easy to use assays providing fast reliable answers based on qPCR
What we lack	Our Screening kit is not covering 100% of the available GMOs (~88%)
Unique Offering	We have a large variety of quantification kits and the capability to launch more assays easily

Sales Tools

Customer-facing Presentations



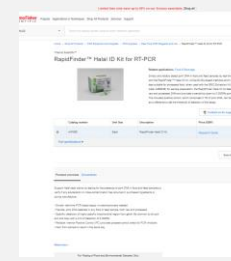
IFUs



Verification Reports



Product Web page



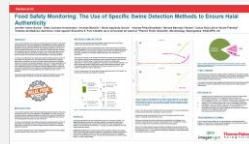
Authenticity Marketing Page



Brainsharks Commercial, Technical and Troubleshooting decks



Posters



Brochure



eSignature





Thank you.

