JRC- TÜBITAK-TAIEX international conference on GMOs detection and analysis

GMO detection and labelling in Belarus

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Biotechnology Regulatory Framework. Food Safety. GMO labelling

The Law "On Quality and Safety of Edible Raw Materials and Foodstuffs to Human Life and Health" of 29 June 2003;

The Law "On Protection of Consumers' Rights" of 9 January 2002:

Consumer has rights to purchase safe food products and to receive comprehensive information on them. In particular, information on commodities must indicate if the food product is genetically modified or contains genetically modified ingredients

Biotechnology Regulatory Framework. Food Safety GMO labelling

- Resolution No. 434 of the Council of Ministers of the Republic of Belarus of April 28, 2005 “On some aspects of consumers information about edible row materials and food products
- Standard STB 1100-98 “Food products. Information for consumers. General requirements” (as amended August 31, 2005)

Accredited laboratories of GMO detection in Belarus

1. Republican Centre of Hygiene, Epidemiology and Public Health
2. Minsk Municipal Centre of Hygiene and Epidemiology
3. Brest Regional Centre of Hygiene, Epidemiology and Public Health
4. Mogilev Regional Centre of Hygiene, Epidemiology and Public Health
5. Gomel Regional Centre of Hygiene, Epidemiology and Public Health
6. Belarusian State Institute of Metrology
7. Brest Centre of Standardization and Metrology
8. Grodno Centre of Standardization and Metrology
9. Gomel Centre of Standardization and Metrology
10. Mogilev Centre of Standardization and Metrology
11. Vitebsk Centre of Standardization and Metrology
12. NAS Institute of Genetics and Cytology
13. NAS Scientific and Practice Centre for Foodstaffs
14. Belarusian State Veterinary Centre

Main regulations on GMO detection in food

- Standard STB R 52173-2005 «Food raw materials and foodstuffs. Method of identification of genetically modified sources (GMS) of plant origin»;
- MUK 4.2.1902-04 «Determination of genetically modified sources (GMS) of plant origin by polymerase chain reaction method». Minzdrav of Russia, Moscow, 2004.
- MUK 4.2.1913-04 «Methods of quantitative determination of genetically modified sources (GMS) of plant origin». Minzdrav of Russia, Moscow, 2004.

List of edible raw materials and foodstuffs, which are subject to control for presence of genetically modified constituents (components) (Annex 1 to Resolution No. 12/26 of June 8, 2005 of the Ministry of Heath Protection and Committee on Standardization)

- **Soya**: 1. Soy beans 2. Soy sprouts 3. Concentrate of soy protein and its texturized forms 4. Isolate of soy protein 5. Hydrolizate of soy protein 6. Soy flour and its texturized forms 7. Milk substitute (soy milk) 8. Sublimated milk substitute (sublimated soy milk) 9. Canned soya 10. Boiled soy beans 11. Fried soy beans 12. Fried soy flour 13. Products received from or with the use of isolate of soy protein, concentrate of soy protein, hydrolizate of soy protein, soy flour, and sublimated soy milk. 14. Fermented soy products 15. Soy paste and products thereof 16. Soy sauce 17. Products received from or with the use of soy milk (tofu, fermented beverages, ice-cream, mayonnaise, etc.)

- **Corn:** 1. Corn for immediate consumption (flour, cereal, etc.) 2. Frozen and canned corn 3. Popcorn 4. Corn chips 5. Mixed flour, containing corn flour

Global area of main biotech crops, million hectares (ISAA,2008,2009)

Crop	2007		2008	
	Area	%	Area	%
Soybean	58.6	51.3	65.8	52.6
Maize	35.2	30.8	37.3	29.8
Cotton	15.0	13.1	15.5	12.4
Canola	5.5	4.8	5.9	4.7
Total	114.3	~100	124.5	99.6

Results of the monitoring GMOs in food (Belarus, June-November, 2008 г)

Crop	Samples analyzed	Positive samples (%)
Soya	2482	61 (2,25%)
Corn	1860	1 (0,05%)
Rice	332	0
Tomato	486	0
Potato	526	0
Rape seed (canola)	29	0
Total:	5715	62 (1,08%)

The main method of control of GM products in Belarus is PCR detection of CaMoV 35S promoter

- For the end of 2008 it was authorized

  13 transgenic events of soyabean. 11 of them (84,6%) contain 35S promotor (www.agbios.com).

  Do not contain 35S promotor : MON89788 (authorized in 2007) and DP356043 (authorized in 2008)

  At present GTS 40-3-2 (RR) soya dominates on the Belarusian market
- For the end of 2008 it was authorized

  40 transgenic events and hybrids of maize. 36 of them (90%) contain 35S promotor (www.agbios.com).

  Do not contain 35S promotor : GA21, MIR604, LY038, 3272.

  At present only MON 810 is very rarely detected in food and feed in Belarus

Differences between GMO-detection legislation in Belarus and European Union, Russia

- **There is threshold 0,9% of technically unavoidable presence of GMOs in food in EU and Russia. In Belarus non threshold system of GMO labelling is available.** This makes it possible to use simple and not too expensive methods for GMO detection. Thus, it makes it possible to use **total** investigation of soybean and corn foods from above mentioned list.

Differences between GMO-detection legislation in Belarus and European Union, Russia

- Belarusian legislation, in contrast with that of the EU and Russia, does not require special registration procedures for transgenic plant varieties (events) intended for food, feed and processing purposes (only for growing). If the food was produced from a transgenic crop variety registered, for example, in the USA, and grown in the USA in accordance with national biosafety legislation, there is no reason to consider such food as hazardous to health.

Ways for improving GMO detection legislation in Belarus

- Expanding the list of foods to be investigated by GMO detection
- Introduction of threshold 0.9% for GMO labelling

Results of the monitoring GMOs in food (Belarus, June-November, 2008 г) have shown that we haven't got reasons to expand the list of foods to be investigated by GMO detection

Crop	Samples analyzed	Positive samples (%)
Soya	2482	61 (2,25%)
Corn	1860	1 (0,05%)
Rice	332	0
Tomato	486	0
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Total:	5715	62 (1,08%)

Introduction of threshold 0.9% for GMO labelling is associated with:

- Dramatic modification of Belarusian biosafety legislation and GMO labelling legislation (introduction of the system of transgenic event registration for food and feed purposes)
- Dramatic modification of Belarusian GMO detection system (total investigation of foods for GMO presence is not possible).
- Dramatic rise in the cost of analysis for GMO detection.

In addition, the kits of chemicals are not available for identification and quantification of 12 transgenic events from 17 authorized in Russia as well as for all the rest which are not authorized. Thus, we haven't got reasons to introduce 0.9% threshold GMO.

- We developed more simple solution of the problem of technically unavoidable presence of GMOs in food: it is proposed to introduce the unified for different methods of GMO detection threshold 0.1% (method sensitivity).
- Sample is considered to be positive if the level of GMOs in it significantly (P=0.05) higher the level of corresponding referent material (ERM 410b: 0,1% GTS 40-3-2 for food with soya and ERM 413b 0,1% MON 810 for food with corn.

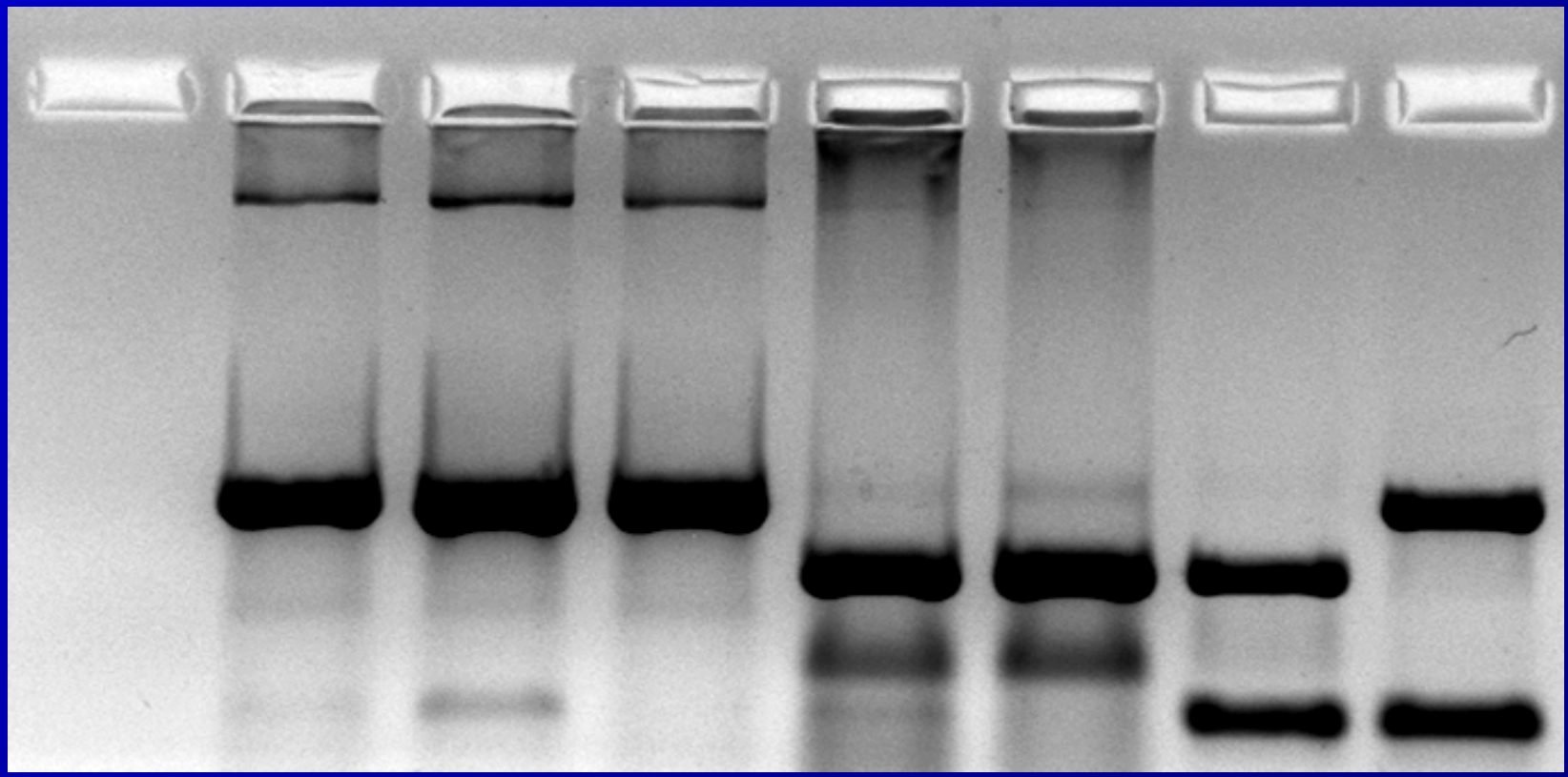
Two methods of GMO detection (CaMoV 35S promoter) are used in Belarus:

- PCR with detection of results by electrophoresis in agarose gel (Standard STB R 52173-2005);

- Real time PCR (MUK 4.2.1913-04) (all the laboratories are equipped with real time amplificators).

Sensitivity of the method of PCR with detection of results by electrophoresis is 0.1% GMO (35S promotor) which is conformed by analyzing above reference materials:

K - 413b 411b 413a 410b 410a Soya^{+} Maize^{+}



Detection and quantification of GM-soya (35S promotor) (r^2=0.9781)

Sample	35S Ct	Int K Ct	dCt	Average dCt	St dev dCt	% GMO
ERM410a (<0.03%)	34.6	19.5	15.1	15.05	0.07	0.00*
ERM410a (<0.03%)	34.7	19.5	15.0			
ERM410c (0.5%)	28.5	20.0	8.5	8.65	0.21	0.55
ERM410c (0.5%)	28.1	19.3	8.8			
ERM410e (2.0%)	26.2	19.4	6.8	6.55	0.35	2.79*
ERM410e (2.0%)	26.0	19.7	6.3			
St 0.1% (ERM410b)	34.7	24.3	10.4	10.95	0.78	0.09
St 0.1% (ERM410b)	35.5	24.0	11.5			
St 1.0% (ERM410d)	31.6	24.4	7.2	7.45	0.35	1.38*
St 1.0% (ERM410d)	31.6	23.9	7.7			
St 5.0% (ERM 410f)	24.7	18.6	6.1	6.1	0.00	3.95*
St 5.0% (ERM 410f)	24.6	18.5	6.1			

Detection and quantification of GM-corn (35S promotor) (r^2=0.9994)

Sample	35S Ct	Int K Ct	dCt	Average dCt	St dev dCt	% GMO
ERM413a (<0.02%)	33.3	18.9	14.4	14.05	0.49	0.00*
ERM413a (<0.02%)	33.1	19.4	13.7			
ERM413c (0.5%)	27.2	19.3	7.9	7.75	0.21	0.26
ERM413c (0.5%)	26.8	19.2	7.6			
ERM413d (1.0%)	27.3	20.9	6.4	6.50	0.14	2.79*
ERM413d (1.0%)	27.5	20.9	6.6			
St 0.1% (ERM413b)	30.7	20.9	9.8	9.00	1.13	0.1
St 0.1% (ERM413b)	29.7	21.5	8.2			
St 1.0% (ERM413d)	27.0	21.4	5.6	5.95	0.49	1.06*
St 1.0% (ERM413d)	28.2	21.9	6.3			
St 5.0% (ERM413f)	25.6	21.6	4.0	4.0	0.00	4.84*
St 5.0% (ERM413f)	24.3	20.3	4.0			

Distribution of positive samples of food containing GM soya according the level of GMO content (35S promoter) (RCHEPH, 2008)

Number of samples (%), containing GMOs		
<0.1%	0.1-0.3%	>0.9%
4 (14.3%)	**18 (64.3%)**	**6 (21.4%)**

- **MU 2.3.2.1917-04:** 8.2. Scheme of the analysis: DNA extraction– Plant DNA detection – Detection of regulator repeats, marker genes – Identification of transgenic event– Quantification of GM DNA

- **Proposed scheme:** DNA extraction– Plant DNA detection – Detection of regulator repeats, marker genes (PCR with electrophoresis or RT PCR)– Conformation of positive result (RT PCR): comparison of sample dCt with dCt of corresponding reference material (0.1% GMO)

Use of this sheme makes it possible:

- Clearly distinguish between “positive” and “false positive” samples;
- To make single meaning decisions, which are statistically substantiated;
- To reduce the disputes arising from different sensitivity of the used analytical methods;
- To use equipment and programs which are already available, as well as kits and reference materials;
- To spare a lot of money for the decision of the problem of technically unavoidable admixture of GMOs (“false positive” samples).

Thank you