



MINISTERIO  
DE SANIDAD  
Y CONSUMO



agencia  
española de  
seguridad  
alimentaria

SPANISH FOOD  
SAFETY  
AGENCY(AESA)

CENTRO NACIONAL DE ALIMENTACIÓN

# GMO Foods in Spain.

## Risk Assessment and Enforcement aspects



# GMOs FOOD ASSESSMENT

- EU Regulation on GMOs
  - Procedures for the authorisation and supervision of genetically modified food and feed REGULATIONS (EC) No 1829/2003 and (EC) No 1830/2003

# GMOs FOOD ASSESSMENT

- Risk assessment. Food safety issues
  - Spanish Food Safety Agency AESA has not own assessment protocole

# GMOs FOOD ASSESSMENT

- Risk assessment. Food safety issues
  - Spanish Food Safety Agency AESA preferes an EFSA central evaluation in GMO.
  - AESA is not reluctant on EFSA GMO risk assessment

## AESA Surveillance

- **National Coordinated Surveillance AESA-Regional Authorities**
- **AESA National Reference Lab (National Centre for Food, CNA) carried out non enforcement controls besides enforcement ones**

## AESA Surveillance

- **CNA is accredited to ISO EN 17025 for GMO Maize and Soya analyses :**
  - **Soya RR**
  - **Maize T25**
  - **Maize MON810**
  - **Maize Bt 11**
  - **Maize Bt 176**
  - **Maize NK603**

PRODUCTO/ MATERIAL A ENSAYAR	ENSAYO
Alimentos y piensos con contenido vegetal	Detección de maíz y/o soja transgénicos (p-35s) mediante PCR simple
	Detección de maíz y/o soja transgénicos (T-nos), mediante PCR simple
	Detección de soja ( <i>gen Lectina, Le1</i> ) mediante Nested-PCR
	Detección de soja transgénica ( <i>gen cp4 epsps</i> ), mediante Nested PCR
	Detección de maíz ( <i>gen Invertasa, Ivr 1</i> ), mediante PCR simple
	Detección de maíz transgénico ( <i>gen cry1A (b)</i> ) mediante Nested-PCR
	Detección de maíz transgénico Bt 176 (CDPK-cry 1A (b), mediante PCR simple
	Detección de maíz transgénico Bt 11 (IVS6-cry1A (b), mediante PCR simple
	Detección de maíz transgénico Bt 11 (35s-IVS2-pat), mediante PCR simple
	Detección de maíz transgénico MON810 (Hsp 70-cry1A (b)), mediante PCR simple
	Detección de maíz transgénico T25 (35s-pat), mediante PCR simple
<p>Soja y maíz transgénico , mediante PCR cuantitativa en tiempo real</p> <ul style="list-style-type: none"> <li>-soja RR (cp4-epsps) LC=0,05%</li> <li>-maíz Bt 176 (PEPC-cry1A (b)) LC=0,05%</li> <li>-maíz Bt 11 (IVS2-pat) ) LC=0,05%</li> </ul>	



<b>Food</b>	<b>Assay</b>
<b>Alimentos y piensos con contenido vegetal</b>	<b>Determinación cualitativa de maíz transgénico Roundup Ready®, evento NK603, mediante PCR simple.</b>
<b>Alimentos y piensos con contenido vegetal</b>	<b>Determinación cuantitativa de maíz transgénico MON810 (35s-Hsp70) mediante PCR en tiempo real con tecnología Taqman™. LC = 0,05%)</b>

## AESA Surveillance

- **CNA methods on GMOs detection:**
- For screening purposes two methods validated by the JRC are used to detect the 35s-promoter and the nos-terminator.
- Several methods have been developed and validated by the laboratory staff for the detection and identification of Roundup Ready®-soybean, Bt 176-, Bt 11,- MON810-, T25-, Starlink-, NK603- and GA21-maizes, respectively.
- Real-Time quantitative PCR methods have been developed and validated by the laboratory for determination of Roundup Ready®-soybean, Bt 176-, Bt 11-, MON810- and T25 maize.
- All these methods have been validated inhouse according to the criteria laid down in ISO-standards and according to guidelines elaborated by the JRC, Ispra.

## AESA Controls

Laboratory	Number of samples analysed		Number of samples identified as containing GMO DNA following qualitative analyses. (%)
	Samples from Spanish market	Samples from Border Inspection Posts	
CNA Results from 2000 to 2002	306	58	125 (34 %)

# GMOs Controls

**84 samples of products containing maize or soybean were analysed in 2002.**

**58 samples were provided by the Border Inspection Posts and concerned products from third countries**

**2 samples were provided by Autonomous Communities**

**24 samples were bought on the market.**

**DNA from Roundup Ready®-Soybean, from Bt176-Maize or from other GMO was identified in 41 samples.**

## AESA Controls

<b>Laboratory</b>	<b>Number of samples analysed</b>		<b>Number of samples identified as containing GMO DNA following qualitative analyses (%)</b>
	<b>Samples from Spanish market</b>	<b>Samples from Border Inspection Post</b>	
<b>CNA Results from 2003 to 2005</b>	<b>232</b>	<b>86</b>	<b>54 (17%)</b>

# AESA Controls

- **SPECIFIC STUDIES:**
- **45 samples provided by the Border Inspection Posts and concerned maize or maize derived products from third countries were analyzed for Bt10 detection. All of them result negative.**
- **15 samples of papaya were analyzed for MG papaya detection. All the results were negative.**



# Additional Information

**FINAL REPORT OF A MISSION  
CARRIED OUT IN SPAIN FROM  
24/02/03 TO 28/02/03**

**DG(SANCO)/9103/2003 – MR Final**

**FINAL REPORT OF A MISSION  
CARRIED OUT IN SPAIN  
FROM 07/03/05 TO 11/03/05**

**DG(SANCO)/7632/2005 – MR Final**