

# Avosetta Meeting on GMOs Siena, 29-30 September 2006

## Portuguese Report

Alexandra Aragão

### 1. Historical context

The first national Law on GMO was Decree-law n. 126/93, transposing Directives 90/219 and 90/220.

In 1993 the first authorizations for research on GMO plants were given.

Between 1993 and 1999 the number of GMO fields in Portugal raises considerably.

		Company/ notification (year)	Culture period	Area in m <sup>2</sup>	Municipality
Tomato ( <i>Lycopersicon lycopersicum</i> )	Change in maturation characteristics	Idal-Heinz 1993 and 1994	Spring– Summer	350 m <sup>2</sup>	Vila Franca de Xira
Patato ( <i>Solanum tuberosum</i> )	Resistant to the potato plant moth	Germicopa 1993, 1994 and 1995	May – November	1993 - 800 m <sup>2</sup> 1994 - 500 m <sup>2</sup> 1995 - 1500 m <sup>2</sup>	Torres Vedras
Maize ( <i>Zea mays</i> )	Tolerant to herbicide ("glufosinato de amónio")	AgrEvo e Pioneer 1997 and 1998	March – November	1997 - 4440 m <sup>2</sup> 1998 - 19700 m <sup>2</sup>	Alpiarça, Golegã, Santarém, Montemor-o-Velho
Maize ( <i>Zea mays</i> )	Resistant to the maize woodworm	Pioneer Hi-Bred 1997 – 1998	March – November	1997 - 1330 m <sup>2</sup> 1998 - 20000 m <sup>2</sup>	Alpiarça, Golegã
Eucaliptus ( <i>Eucalyptus globulus</i> )	Genetic marker	Stora Celbi 1997	May 1998 May 2001	3150 m <sup>2</sup>	Óbidos
Maize ( <i>Zea mays</i> )	Resistant to the maize woodworm	Novartis 1998	April – October	12000 m <sup>2</sup>	Viana do Castelo, Amares, Coimbra, Celorico de Basto
Patato ( <i>Solanum tuberosum</i> )	Change of the phosphate metabolism	Instituto de Tecnologia Química e Biológica 1998	Spring	200 m <sup>2</sup>	Santarém
Maize ( <i>Zea mays</i> )	Tolerant to herbicide ("glufosinato")	Monsanto 1998 e 1999	May-December	1998 - 7000 m <sup>2</sup> 1999 - 8500 m <sup>2</sup>	Póvoa do Varzim, Elvas
Maize ( <i>Zea mays</i> )	Resistant to the maize woodworm	AgrEvo 1999	May	1200 m <sup>2</sup>	Mora

In February 1999, for the first time, the Ministry of Agriculture authorizes the inscription of s varieties of Bt maize (*Bacillus thuringiensis*) in the national catalog of seed varieties for commercialization.

Several farmers associations asked the Government not to accept more GMO tomato seeds and not to authorize more maize fields.

In 1997, Greenpeace together with “Quercus”, one of the most active environmental NGOs in Portugal, have organized a public demonstration against an American ship (*Pacificator*) transporting transgenic maize, while it was anchored in Lisbon port.

As a consequence, an inter-ministerial group of experts to advise the Government on GMOs was created.

In March 1999 a known magazine “Proteste” own by the largest consumers’ association (Deco) published an article denouncing the existence of unlabeled food containing traces of GMO ingredients in the Portuguese market. This caused public protests and raised the consumers’ suspicions.

In April 1999, when the Government approved two more varieties of maize (*Elgina* and *Compa CB*) for commercial purposes, and when it became public that 15 more varieties were to be authorized, a “Platform” gathering 23 environmental NGOs and biological farmers associations was created. The importance and ascendancy recognized to this “Platform”, lead to a Ministerial Dispatch suspending the assessment of new GM

varieties, as well as the inscription of the variety “*Elgina*” and “*Compa Cb*” in the National Catalog of seed varieties for commercialization.

The owner of the authorization attacked this decision before the Supreme Administrative Court but the Court decided in favour of the Ministry.

As a consequence, not only the assessment of new varieties and the inscription in the Catalog but also the production (which, at the time had reached the 1300 hectares of maize) were suspended.

Short after the approval by the Commission, in September 2004, of 17 varieties of GM maize an interim measure for “suspending, for reasons of precaution, the production of transgenic maize in Portugal” was raised (in March 2005), before the Administrative Court in Lisbon. The interim suspension was declared, but the final decision was not favourable.

Between April 2005 and today 11 municipalities (in 305) have declared to be GMO free.

## **2. National regulatory approach to GMO in Portugal**

Portuguese laws on GMO follow closely the European regulatory approach.

There is no general Act on GMO and the structure of the national system is similar to the European one, since, as a rule, there is one national law corresponding to one European Directive or regulation.

- Decree-law n. 2/2001, on the confined use of GMOs for the purpose of protecting human health and the environment, transposes Directive 98/81.
- Decree-law n. 72/2003 (modified by Decree-law n. 164/2004), on the deliberate release of GMO to the environment, and the placing in the market of products that contain GMO, in accordance with the precautionary principle and for the purpose of protecting human health and the environment, transposes Directive 2001/18;
- Decree-law n. 154/2004, approves the National Catalog of Agricultural and Horticultural Varieties and adopting the principles and conditions for certification of seeds (including GMO) and for their commercialization, transposes Directives 2002/53, 2002/55 (modified by Directive 2003/90, 2003/91, and Regulation 1829/2003).
- Decree-law n. 168/2004, on traceability and labeling of GMO and on the traceability of food and feed, implements Regulation 1830/2003;
- Decree-law n. 102/2005, on food and feed, implements Regulation 1829/2003.
- Decree-law n. 36/2006 on transboundary movements of GMO, implements Regulation 1946/2003.

Other important legal acts not referring directly any European norms are:

Decree-law n.160/2005, regulating the coexistence of GMO production with conventional cultures and biological production.

Decree n° 904/2006, on the conditions and proceedings for establishing GMO free areas.

## **3. Executive competencies in the Member States**

Portugal is a centralized State with only two Autonomous Regions (Azores and Madeira) and all the competences related to GMO belong directly to Governmental departments or to Public Institutes indirectly tutored by the Government.

### 3.1. Directive 98/81

In what concerns Directive 98/81 (Decree-law n. 2/2001) four entities share supervision competences for the confined use of GMO:

The **Environment Institute** and the **General Environmental Inspection**, both public centralized organs directly dependent from the Ministry of the Environment, Territorial Planning and Regional Development.

The **National Health Institute** and the **Institute for Labour Safety, Hygiene and Health**, both decentralized public institutes belonging to the indirect administration of the State, over whom the Government (through the Ministry of Health and the Ministry of Social Security and Labour) only has light tutorship powers.

The **Environment Institute** has a wide range of competences:

- receives the notifications for confined uses of GMO,
- decides how stringent the protective measures should be,
- requests further information on the operation to be carried out,
- decides what information should be kept confidential,
- promotes, whenever it considers necessary, a public consultation before deciding on the contained use of GMO,
- authorizes the start and determines the end or suspension of the confined use,
- inspects the facilities,
- verifies the adequacy of confining measures, the correctness of waste management, the existence of emergency procedures, the sufficiency of protection measures,
- imposes a change to tighter confining conditions,
- consult the competent authorities of the Member States likely to be affected in case of accident in what concerns the execution of emergency plans,
- gives publicity to the correct procedures to be followed in case of accident,
- in case of an accident, informs the Commission and the competent authorities of the affected Member States, makes sure protective emergency measures are adopted, and recommends future measures to prevent new accidents,
- acts in coordination with the other authorities,

The **National Health Institute** is consulted by the Environment Institute before taking any decision.

The **General Environmental Inspection** and the **Institute for Labour Safety, Hygiene and Health** supervise the activities developed under this law in their specific fields of competence, apply fees and preventive measures (like seizure of the equipment, paying financial bonds, suspending the activity temporarily, preventive shutting down of installations).

### 3.2. Directive 2001/18

Again it is the **Environment Institute** who concentrates the majority of the competences regarding the release of GMO to the environment and their placing in the market:

- receives the notification,
- requests further information,

- promotes a public consultation or a consultation of specific interest groups
- decides on the authorization, suspends it, withdraws it or authorizes its renewal,
- in case of new information on risks to human health and the environment, discloses it to the public, informs the Commission and the competent authorities of the other Member States,
- changes the conditions of the authorization,
- inspects and controls the release and placing in the market operations,
- keeps public records on the operations,
- makes sure corrective measures are taken when necessary,
- prepares an assessment report and sends it to the promoter and to the Commission,
- conditions the product's use according to its danger to the ecosystems and to the environment,
- verifies whether the labeling and packaging conditions, respect the conditions set out in the authorization,
- raise objections to authorization processes going on in other Member States,
- can set a limit below which no labeling is necessary,
- decide which information are to be kept secret,
- every three year prepare a report to the Commission on the implementation of GMO law,
- check whether the GMO involving risk of antibiotic resistance are banned

Before every decision, one of two specialized entities have to be consulted: **Directorate-General for Health** (a department of the Ministry of Health) and, in the case of GM superior herbs or plants, the **Directorate-General for the Protection of Cultures** (a department of the Ministry of Agriculture).

The **General Environmental Inspection** supervises compliance with this law and can impose fees and adopt preventive measures: again seizure of the equipment, paying financial bonds, suspending the activity temporarily, preventive shutting down of installations and fields.

Besides the fees, the **General Environmental Inspection** can also impose additional sanctions: loss of objects, interdiction of an activity, denial of subsidies and other benefits, no right to participate in public competitions, shutting down installations and field destruction.

### 3.3. Regulation 1829/2003

The general competence to supervise compliance with the Regulation lays on the **General Environmental Inspection**.

In what concerns the compliance with obligations related with seeds and plant propagation, it's the **Directorate-General for the Protection of Cultures** who is competent.

As to raw materials, ingredients, additives and food, it's the **Authority for Food and Economic Safety** a centralized service of the State, directly dependent of the Ministry of Economy.

Finally, for the obligations that have to do with raw materials, additives and feed, the **Directorate-General of Veterinary**, a department of the Ministry of Agriculture.

### 3.4. Regulation 1830/2003

The competences regarding Regulation 1830/2003 belong to two departments of the Ministry of Agriculture: in relation to food, the **Directorate-General for Fiscalization and Control of Food Quality** is competent; in relation to feed, it's the **Directorate-General of Veterinary**.

## 4. Implementation and enforcement of Directive 2001/18

### 4.1. Precautionary principle

The Portuguese law on the release of GMO to the environment refers to precaution almost as much as Directive 2001/18 does:

Neither a concept nor a positive definition of a *minimum content* for the precautionary principle is given.

A brief reference to the principle is included in the preamble and in article 1 (“in accordance with the precautionary principle”). Some stronger hints are found in Annex II on “Principles applicable to the assessment of environmental risks”, under B) “General principles”.

In some contradiction with the precautionary principle, two legal options are rather opened to criticism:

1. only negative decisions must be justified. If the competent authorities decide to accept the notification, to authorize the release or the placing in the market or to renew the authorization, no justification is needed. On the other hand, if they decide not to authorize or nor to renew, this decision has to be specially grounded. This seems to represent an implicit presumption of safety contrary to the precautionary principle.
2. it is likely that the 10 years as a maximum period for authorizations will tend to be the “normal” period. Why? Because according to the law the 10 years period can be “enlarged or reduced for specific reasons” (these reasons are not specified).

### 4.2. Risk assessment and scientific bodies

On risk assessment the Portuguese law transcribes the annexes of the directive. It is the notifier's responsibility to perform risk assessment in conformity with annexes II and III. The proposed procedures for risk assessment shall be described in the notification and are submitted to an approval or rejection decision by the competent authority.

For the adoption of the law on the release of GMO to the environment itself, some scientific bodies (as well as environmental NGOs and professional associations) have been heard. Yet, in the authorization procedures their involvement is not obligatory.

The mandatory support of scientific bodies is limited to the right of the competent authority to ask the Commission to consult the Scientific (and ethical) Committees “existing in the European Union” (corresponding to article 28/2 of the directive).

In March 2004 a Commission for the Assessment of Risks for the Use of GMO was created. It is an inter-ministerial Commission, with representatives from the Ministry of the Environment, the Ministry of Agriculture, the Ministry of Health, and a representative of the President of the Council of Ministers.

Individual experts or experts representing organs with particular interest in this matter may also belong to the Commission without a right to vote “in any case”.

The Commission coordinates the different Ministries, issues non binding opinions (of its own initiative or by request of the Environmental Institute), asks individual experts or specialized organs for opinions and takes care of the publication and diffusion of information.

### 4.3. Authorization procedure

The authorization procedure is rather a centralized. Three public bodies are involved in this procedure:

- the **Environment Institute**, called in the law “the competent authority”, who takes all the relevant decisions,
- the **Directorate-General for Health** or the **Directorate-General for the Protection of Cultures**, who are consulted but whose opinions are not binding for the **Environment Institute**.

The involvement of the public or “whenever adequate” of the stakeholders is a mandatory step.

### 4.4. Self-monitoring and supervision

Self-monitoring is foreseen in the same terms of the directive.

The notifier must present, along with the notification, a self-monitoring plan according to Annex VII (equal to the directive’s annex) which can be approved by the competent authority.

Competent for supervision is the **General Environmental Inspection** which lacks both human and financial resources to perform acceptable inspection activities. This insufficiency of means lead the Parliament (in July 2000) to pass on a Resolution on the labeling of GMO food and feed: “1. The Republic Assembly recommends the Government to arrange the full accomplishment of the legal duty to provide for a detailed labeling of all food produced on the basis of GMO or including GMO. 2. This legal duty shall be extended to animal feed”.

There are some active NGOs acting informally in this field (<http://www.stopogm.net>).

### 4.5. Safeguard clause

The safeguard clause has been received in the Portuguese law under the titles “Procedure in case of new information” and “Community procedure in case of objections”.

If the competent authority has access to information that can have meaningful consequences on human health and the environment after the authorization has been

issued, it sends an assessment report to the European Commission within 60 days. In this report the competent authority expresses its opinion on whether the conditions of the authorization should be changed or if the authorization should be withdrawn. The case where the competent authority nevertheless authorizes the operation is clearly described in the following norms.

However, although the temporary interdiction of the activity, and the suspension or revocation of the authorization in case of new information on risks are recognized as powers of the competent authority, these extraordinary situations are neither described nor even mentioned in the law.

One of the weakest points of this regime is the delay for taking a decision in the case where the authorization is changed (this is the only case described in detail, no deadlines for suspending, interdiction or withdrawing the authorization). Considering that the competent authority has 60 days after getting of the new information to notify the Commission (this is not “immediately” as in the directive 23/1§3), that it also has 60 days stating in the same point (after getting the information) to decide on the changes in the authorization, and that it has 30 more days to notify the operator about these changes, the final delay is, at least 90 days.

So, there may be no time left for the Commission to decide on the case.

On the other hand, the delay for solving “pending questions” being 75 days the final delay in these cases is 105 days.

If the Commission or other Member States raise objections the delay for taking a final decision are 120 days plus 30 to notify the operator, the Commission and the other Member States, resulting in an overall delay of 150 days.

#### **4.6. Transparency and participation**

In the law transposing 2001/18 Directive, there are three norms on transparency and participation: one on “information of the public” another on “publication” and the other on “public consultation”.

The essential information released to the public consists (at least) on:

- the authorization or its renewal (this information must be published in the official journal, *Diário da República*);
- the monitoring results,
- the records on the localization of the GMO fields
- the information on illegal releases or illegal placing in the market (without authorization)

The fact is that in practice, this information is not easily available and that in some cases there has to be a complaint to the Commission on Access to Administrative Documents (CADA) to gain access to relevant information.

In what concerns public participation, formal consultation within a certain period is the only means of participation previewed in the law.

For the purposes of consultation, the information contained in the notification (with the exception of confidential information) is available to the public.

The address of the exact place where the notification can be read, the timetables and the total length of the consultation period is advertised in one announcement in two national newspapers and, whenever possible in one local or regional newspaper, as well as through the Internet.

The public consultation should take place before the final decision, for a period of less than 60 days. The public's opinions shall be taken in consideration by the competent authority.

In July a new law transposing Directive 2003/4 was approved.

Now the public authorities must release to the public the lists or records on environmental information available (including GMO), support the public in the access to information, deliver the information by means of telematic "when applicable", and so on and so forth.

No meaningful differences can be felt yet.

#### **4.7. Court review**

Court review is allowed in very wide terms, since popular action is recognized.

There is legal standing for any association or persons wanting to defend the environment (the same regime is applicable for the protection of the heritage, cultural, natural, architectural, etc).

#### **4.8. Penalties**

The law provides for administrative sanctions.

There is a fine to be paid ranging from €498,80 to €3740 in the case of individuals, and from €2494,10 to €44891,81 in the case of an undertaking.

Additional sanctions can be applied according to the importance of the fault and the guilt of the agent: loss of objects, interdiction of an activity, denial of subsidies and other benefits, no right to participate in public competitions, shutting down installations and field destruction.

Negligence and attempt are also punishable.

Civil sanctions are not foreseen but are applicable given the general conditions are present.

### **5. Authorisation of the placing on the market of GMOs**

#### **Authorizations other than food and feed**

The law on clinical essays of human medicines includes essays with GMO and does balance the benefits against the expected risks: "The essays depend on a previous assessment concluding that the potential individual benefits for the participant in the essay, as well as the benefit for other participants, present and future, overcome the eventual predictable risks and troubles".

Precaution is not mentioned in the law but is underlay the legal regime considering the procedures and the cautions necessary before an essay is authorized.

It is not mandatory to consider the differences in climatic or geographical conditions.



There is no public participation but only experts' opinions.

The law on fitopharmaceutical substances also demands risk assessment and balances benefits and risks: the product shall be accepted if "on the basis of an assessment of a large set of scientific data showing that the product is efficient for the purposes that it is intended for and does not present a unacceptable risks for human and animal health and for the environment".

However, showing how difficult it is for the authorities to keep up with the technical advances and perform a reliable supervision, a very recent law (of the 26<sup>th</sup> September 2006) declared that "the fitosanitary inspection procedures have to be adapted in order satisfy real needs at the light of new sanitary risks".

Similarity in climatic and geographical conditions is considered for the recognition of authorizations issued in another Member State.

Again, there is no public participation but many specialized organs are involved.

### **Authorizations for food and feed**

The law adopted to implement Regulation 1829/2003 doesn't say much. It determines the taxes to be paid for the analyses of the notification processes. For all the other questions, the general law (transposing Directive 2001/18) is applicable.

## **6. Coexistence**

There is a specific Decree-law approved in September 2005, for the purpose of regulating co-existence of conventional cultures and biological cultures with GMO cultures.

This diploma applies to the GM varieties that are inscribed in the Catalogues of Common Varieties of Agricultural and Horticultural Species and in the National Catalogue of Varieties of Agricultural and Horticultural Species.

The measures are applicable from the acquisition and reception in the agricultural installation of the GM seeds (including warehousing) to the delivery, by the farmer, of the vegetable products in the installations for placing in the market or for processing.

Besides the general obligations to fulfill the technical norms (Anex I), and to allow official entities free access to the fields and installations, the farmers wishing to breed GM varieties must fulfill certain requirements:

1. Participate, before the purchase of the GM varieties, in courses or specialized formation initiatives in order to develop the necessary skills. The content of the courses is approved by the Directorate General for the Protection of Cultures. A record of all those participating in the courses shall be kept and sent to the Regional Directorate for Agriculture.
2. Notify the farmers organizations that he belongs to (or, in the case of an individual farmer, the local Regional Directorate for Agriculture) 20 days before breeding starts of the nature of GMO to be used, exact location of the filed and co-existence measures to be taken (any changes shall also be notified).
3. Inform the neighbour farmers, in writing, whether they breed the same variety or not, of his intention, 20 days in advance. The neighbour farmers are those whose fields are less than 200 meters apart (in the case of conventional cultures) or 300 meters (in the case of biological cultures), or

Those who share any agricultural equipment with the concerned farmer.

Annex I sets out the technical norms for cultivation of GM varieties and n.2 determines the measures for reducing the fortuitous presence of pollen or mechanical mixing.

There are three ways to prevent the fortuitous presence of pollen:

1. The definition of a minimal distance for isolating the cultures. The distance is 200 m in the case of conventional cultures and 300 meters in the case of biological cultures.

2. Maize border lines:

The 200m distance can be replaced by 24 maize border lines

The 300m distance can be reduced to 50m if 28 maize border lines are cultivated.

The maize shall be in the same vegetative cycle as the GM culture and it shall be packaged and labeled as GM maize.

3. Use of different vegetative cycles or of differentiated stage seed-time

The choice of varieties with different vegetative cycles and differentiated stage seed-times can be used to avoid coincidence in the flowering and pollination period.

These measures can be excused if:

1. the farmers voluntarily associate to create production areas dedicated exclusively to cultivation of GM varieties, of the same GMO
2. the neighbour cultures are intended to be mixed with the GM culture in lots having the same label as GM varieties.

Here is the present scenery of GMO production in Portugal:

**REGIONAL DIRECTORATE OF AGRICULTURE OF RIBATEJO AND OESTE**

PLACE	VARIETY	AREA (ha)	COEXISTENCE MEASURES
Vale de Figueira	PR34N44	23,36	ID
Vale de Figueira	PR32R43;Cuartal	152,29	ID
Vale de Figueira	PR32R43	48,11	ID
S. Vicente do Paúl	PR34N44	60,00	BL
S. Vicente do Paúl	Elgina;DKC 5784YG;DKC 6041YG	20,00	BL
Rio Frio	DKC 6041YG	12,00	ID
Poçoirão	DKC 6041YG	0,63	ID
Rio de Moinhos	PR34N44;DKC 6575;DKC 5784YG	36,36	ID/LB/SS
Rio de Moinhos	PR34N44;PR32R43	46,40	ID/BL
S. Vicente do Paúl	PR34N44;Elgina (=PR33V08)	10,00	BL
S. Vicente do Paúl	DKC 5784YG;DKC 6041YG	12,00	BL
Carregueira	PR34N44	12,50	ID
Coruche	PR34N44	16,00	ID
Aveiras de Cima	PR32P76	2,00	ID
Santarém	PR32R43;PR32P76;PR34N44; Elgina	0,20	ID

DI- Isolating distance, LB- Border lines, SF- Stage seed-time

**REGIONAL DIRECTORATE OF AGRICULTURE OF BEIRA INTERIOR**

PLACE	VARIETY	AREA (ha)	COEXISTENCE MEASURES
Orjaís-Covilhã	Elgina; PR34N44	26,0	ID/LB

DI- Isolating distance, LB- Border lines

**REGIONAL DIRECTORATE OF AGRICULTURE OF ALENTEJO**

PLACE	VARIETY	AREA (ha)	COEXISTENCE MEASURES
Almograve	PR34N44;DKC 6041YG	23,00	BL
Almograve	PR32R43;DK 6041YG	82,58	SS
Almograve	PR32R43; PR32P76; PR34N43; Elgina	4,00	ID,BL
Alvalade do Sado	PR34N44	24,00	ID
Caia São Pedro	ES Paolis YG*; PR34N44	87,07	ID,BL

Campo Maior	PR32R43	0,25	ID
Campo Maior	PR32P76	49,00	ID
Campo Maior	PR34N44;PR32R43	145,00	ID, BL
Campo Maior	PR34N44	68,00	ID,BL
Cruzamento do Almogrove	DKC 6041YG	16,00	BL, ID
Elvas	PR32P76	18,00	ID
Elvas	PR32P76	6,15	ID
Elvas	PR32R43;PR32P76;PR34N44; Elgina	4,00	ID,BL
Elvas	PR34N44	22,00	DI,BL
Nossa Sr.ª da Tourega	Protect	25,00	BL
V. Nova de Milfontes	DKC6041YG	82,46	BL
V.Nova de Milfontes	DKC6041YG	8,00	BL
Zambujeira do Mar	DKC 6041YG	22,40	BL

DI- Isolating distance, BL- Border lines, SF- Stage seed-time

\* Variety authorized under Commission Decision n. 2004/842/CE

#### REGIONAL DIRECTORATE OF AGRICULTURE OF BEIRA LITORAL

PLACE	VARIETY	AREA (ha)	COEXISTENCE MEASURES
Coimbra	PR34N44	8,0	SS/BL
Figueira da Foz	Elgina	39,9	ID/BL
Carapinheira	PR34N44	22,8	BL
Vagos	PR34N44	10	ID
Seixo	Elgina (=PR33V08)	2	BL

DI- Isolating distance, LB- Border lines, SF- Stage seed-time

#### REGIONAL DIRECTORATE OF AGRICULTURE OF ENTRE DOURO E MINHO

PLACE	VARIETY	AREA (ha)	COEXISTENCE MEASURES
Outiz	DKC6041 YG	2,0	BL

BL- Border lines

Furthermore, the producers or packagers of GM varieties shall include in each package an information leaflet (approved by the Directorate General for the Protection of Cultures) in order to facilitate the farmers' accomplishment of the co-existence, traceability and labeling measures.

The Directorate General for the Protection of Cultures implements a "suite plan" for assessing the execution and respect of the legal norms applicable including in the plan a record of the major difficulties felt by the farmers in respecting the technical norms of Annex I and a record of pleadings between GMO farmers and other farmers.

Administrative sanctions are established: from €250 to €3700 for individual farmers and from €2500 to €44800 for collective entities.

Again, negligence and attempt are punishable and there are similar additional sanctions.

A compensation fund for supporting economic damages from fortuitous contamination will be established. The fund will be financed by the farmers and other entities involved in the productive process.

The possibility of establishing GMO free areas was also foreseen but it hasn't been regulated until September 2006.

According to the new law, "free areas" are agricultural areas in which a certain GM variety is not cultivated by express voluntary decision of all the farmers producing such vegetable in that area.

The “establishment of a free area” is the act of rendering public that in a certain exploration, a set of explorations or a certain area of a municipality GMO are not bread.

The minimum area for being declared “free area” is 3000 adjoining hectares.

The publicity consists on publication in the official paper *Diário da República*, and is promoted by the Regional Directorate for Agriculture after the express voluntary decision of all the concerned farmers or after the decision of the municipality, with the agreement of all the farmers.

The validity of the establishment of a free area is 5 years and is automatically renewed for the same period all things staying the same.

If any change occurs a new request has to be made.

The breeding of GM varieties in the free area leads to the caducity of the free area.

## **7. GMO traceability and labelling**

It is claimed that the national laboratories are not equipped to verify the existence of GMO in food and feed.

Together with the notification the promoter of a placing in the market must present a label proposal which is approved by the Environment Institute.

Again the penalties are administrative sanctions comprehending fees and additional sanctions.

## **8. Directive 2004/35/EC on Environmental Liability**

Directive 2004/35 was not transposed yet.