Italian Ban on GM Maize MON 810

Abstract

Following the request from the local court of justice of Italy, the EFSA provided independent scientific advice on the argument proposed by the Italian government on the prohibiting of the MON 810 maize for cultivation across the Italy. The arguments put forward by the Italian government do not reveal any new information that would invalidate the risk assessment conducted by the EFSA GMO panel on MON 810 and its recommendations for use. The adopting of the 2013 Italian decree is deemed illegal due to the Italian government's failure to follow the procedure outlined under article 34 of regulation (EC) No 1829/2003. Gaps however exist in the current regulations resulting in inconsistency between E.U legislation and legislation of its Member States. It is the recommendation of the GMO panel that the reinstating of MON 810 maize is conducted immediately, the EFSA authorities' regulations on cultivation of GM crops is transcribed into legal text across all Member States of the E.U and the farmers whose GM crops were destroyed under the Italian decree be refunded the cost of damages by the regional government.

Introduction

The objective of this group work as members of the consultancy team was to recommend/ not recommend whether the farmers whose crops and fields sustained extensive damage should be refunded the cost of damages. This damage was a result of the passing of a national decree by the Italian government which was unapproved by the E.U resulting in the destruction of the fields but also included the damage sustained as a result of anti-GM activists. My role as a Scientific Expert on the Genetically Modified Panel for the European Food Safety Authority (EFSA) was to provide independent scientific advice and clear communication representing the view of the European Commission (EC) and address the various proposed risks associated with the GM crop MON 810 Maize put forward by the Italian government as part of its reason for prohibiting GM crop cultivation. My role will also include the assessing of current E.U legislation in relation to the topic, limitations of legislation and the gaps between it and the legislation of its Member States. A number of recommendations will also be provided to bridge any gaps identified. Finally the workload of this team was split in terms of expertise as follows,

- – Environmental Ethicist

Environmental concerns associated with the GM process in terms of environmental impacts and additional possible risks not yet established.

– Plant Scientist

Current and potential influence of the cultivation of Bt-resistant corn on plant diversity in areas already cultivating MON 810 Maize.

– Professor of Agronomy

Factual science behind the genetics of creation, physiology of producing and use of Bt-resistant corn in food and other practices.

– Insect Biologist

Effect of Bt-resistant corn on target and non-target insects in terms of mechanism of exposure and eradication.

– Corn Market Expert

Potential current loss/profit of the corn market upon commercialisation of Bt-resistant corn factoring the reduction of herbicides, pesticides and fungicides.

Evaluation of evidence presented by Italian government in banning MON 810 Maize

The maize MON 810 was developed by the applicant, Monsanto Europe S.A, with the aim to express Cry1AB protein, derived from (Bacillus) thuringiensis which has the ability to demonstrate protection against the lepidopteran target pests such as the European Corn Borer (ECB) and the Mediterranean Corn Borer (MCB) [1]. During 2013, the Italian government passed a decree citing the precautionary principle as grounds to ban the seeding and cultivation of GM crops such as maize MON 810. This decree also cited a number of environmental impact concerns cited by France as additional factors for the ban. The EFSA has since analysed the information submitted by the Italian government and concluded there to be no significant risk to the environment with the minor exception of resistance evolution in lepidopteran target pests[2]. The bioinformatics analysis of the inserted DNA and its flaking regions of the maize MON 810 do not raise any health concerns. Analysis of the expression of the genes introduced as a result of genetic modification demonstrated consistent stability throughout a number of generations [2]. The EFSA also analysed the materials produced from the GM maize and stacked GM maize where the maize is one of the parental lines. With the use of their comparators it was indicated that the GM maize is phenotypically, agronomically and compositionally identical to non-GM maize with the exception of the newly expressed protein illustrating the precision of the method[2]. The Cry1AB protein also shows no homology with proteins known to be toxic or allergenic to humans or animals [2]. While examining these parameters, the EFSA specifically considers regional differences to ensure

consistency. Maize Mon 810 was concluded to present no addition multiplication, dissemination or survival characteristics when compared to conventional maize with the exception of the GM expressed gene.

The EFSA also examined some of the more specific environmental impacts proposed by the Italian government in their decree such as the potential for regional contamination of organic maize with the GM maize, effects on non-target species, effect of pollination species, hazards for water dwelling species, effects on soil organism and finally soil microorganisms with focus on microbial communities [3]. The EFSA found the spread of maize MON 810 in regional locations to be not different to conventional maize and if its recommended management practices are followed, the chance of contamination is low. The effects on non-target natural enemies of corn borers will be very low and changes in these populations at different tropic levels is commonly associated with pest management practices such as pesticide sprayed fields [2]. The EFSA does however agree with the proposal of the Italian evidence that honeybees may face added stresses that could theoretically affect their susceptibility to the Cry proteins produced in the GM maize and sub-sequentially produce indirect hazards on the honeybees. The view of the EFSA however is that this effect is low and that maize MON 810 does not result in reductions of pollinating species when compared with populations of conventional farmed fields. The GMO panel of the EFSA also agrees with the possible hazard proposed to water dwelling species such as Trichoptera. This hazard has been associated with high MON 810 pollen exposure however the EFSA does not believe on the basis of the literature that the pollen concentrations would be of such levels in cultivated fields [4]. The Italian evidence also raises the concern of the risk to soil organisms however; the GMO panel observes this risk to be no different than the common effects of conventional agricultural practices, natural environmental stresses and difference between localities. In terms of soil organisms, it is also highlighted in the Italian evidence the possible negative effects on soil microorganisms and microbial communities. The GMO panel concludes that any potential effects of the GM maize will be transient in nature, minor or localized depending on field conditions and are likely to be similar to common processes associated with conventional farming[2].

The Italian argument is similar of that to the case put forward by France in the prohibiting of MON 810 maize. It is the view of the EFSA that there was no evidence presented in both arguments to undermine the previous safety findings and considered the decision by France and Italy as ‘‘scientifically unfounded’’[5]. In 2009, Germany suspended the cultivation of MON 810 maize on the grounds of two potential environmental impacts also cited by the

Italian Agency for Environmental Protection and Europeans Community, the impacts of force feeding trials on lady birds and daphnia. Through previous data analysed by the EFSA on Lepidoptera, it is the view of the GMO panel that this suspension of cultivation was based on incomplete list of references, ignores the widely admitted case-by-case approach and ultimately confuses potential hazards and proven risks in the scientific procedure of the risk assessment[5].

Current E.U legislation & evaluation of Italy's ''emergency measure'' adoption

In terms of the legislative background on GM crops such as MON 810, this maize product was authorised for all uses under directive 90/220/EEC in the E.U for all applications with the exception of direct food use [5]. In June of 2009, the GMO panel representing the EFSA adopted the scientific opinion proposed on the renewal of regulation (EC) No 1829/2003 on maize MON 810 for impact, processing for feed and indirect food and cultivation[6]. In terms of the approval process for GM crops, this application process is highly regulated. All GMO's in the E.U are subject to extensive, case-by-case and science-based food evaluation by the EFSA in the form of the GMO scientific panel. The GMO panel are responsible and required to report their findings on the application of a particular GM crop for example to the EFSA, this report is consequently reported on by the EFSA to the European Commission (EC) who are responsible for the drafting of proposals for granting or refusing authorisation [3]. This proposal is then submitted under the section of GM food and feed to the Standing Committee on the Food Chain and Animal Health. This proposal can be accepted by the EC or passed onto the Council of Agricultural Ministers. This council can review the case put forward for up to three months, if a majority in favour or against is not reached within this timeline, the proposal is re-passed to the EC and adopted [3]. This application process is outlined in figure 1. Through this highly extensive review processing, as of September 2014, 49 GMO's are authorised in the E.U consisting of 8 GMO cottons, 28 GMO maize's, 3 GMO rapeseed oils, 7 GMO soybeans, 1 GMO sugar beet, 1 GMO bacterial biomass and 1 GMO yeast biomass [3].

Once the application is approved, the applicant must follow extensive guidelines including the annual conduction of a Post-Market Environmental Monitoring (PMEM) report. This report must be in turn presented to the EC and its Member States on an annual basis with the results of its monitoring activities of the cultivation of maize for example [1]. This report is required to cover three main aspects. The results of the Insect Management Plan which

includes data on non-Bt resistant organisms, refugia implementation, evolution of target pest resistance and education of the farming community .

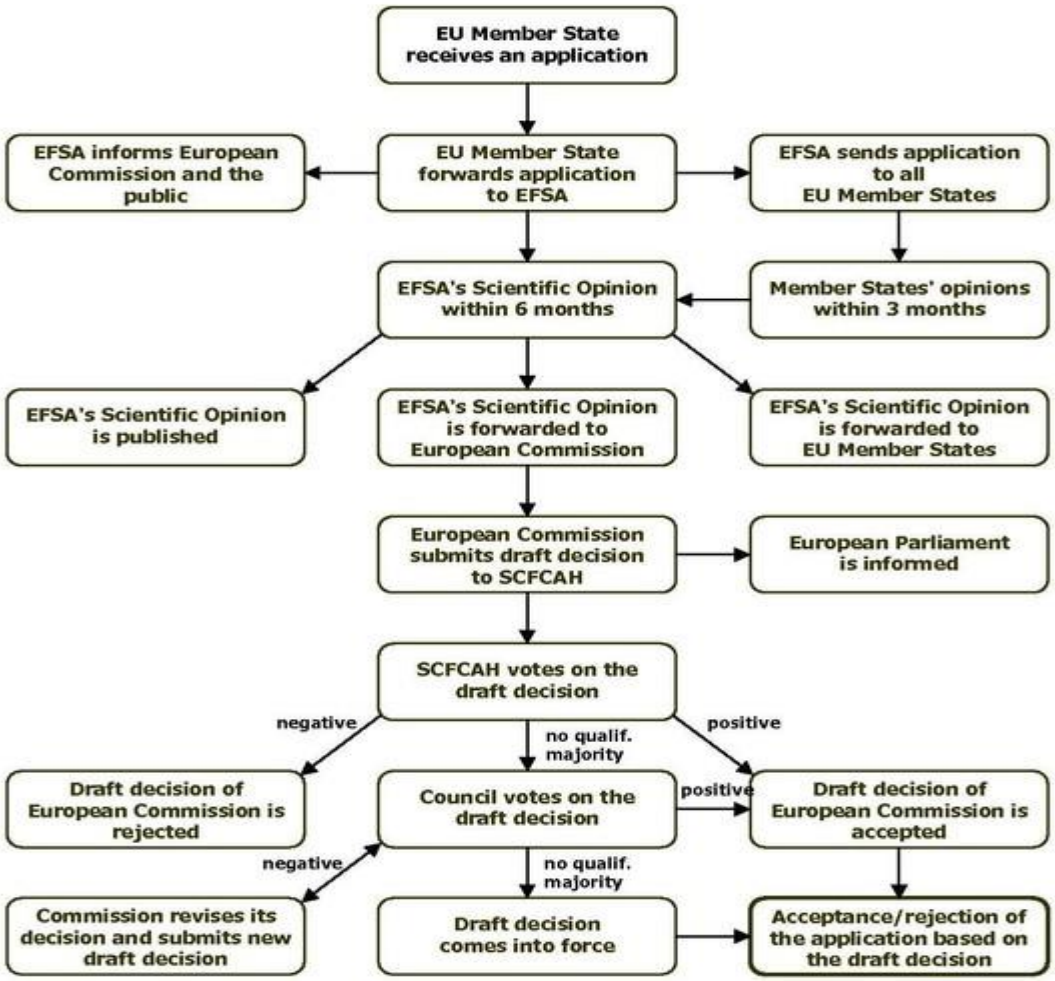

Figure 1.

Schematic description of an application of a new GMO crop to the European Commission[5]

The second aspect involves the General Surveillance Monitoring Program consisting of the analysis of questionnaires completed by selected farmers growing the GM crop and famers of the surrounding area that are not growing the GM crop in various different Member States. Finally as part of this PMEM report, a review of the peer-reviewed publications on the safety of the GM crop must be presented with each annual report. For the case of MON 810 maize, a number of shortcomings in relation to report were identified in 2011 and 2012. A lack of relevant information was evident including raw data and software programming. Failure of some farmers to plant refugia areas was also highlighted which is known as the main cause for the onset of resistance to Bt-maize among target pests. The EFSA recommends in its legislation on MON 810 that the implementation of refugia areas is paramount as it will allow

Bt-resistant pests to mate with susceptible individuals to produce a heterozygous progeny that is phenotypically susceptible to the GM crop. This high dose/refugia strategy is stated in the legislation produced by the EC in order to limit evolution of resistance[5]. A lack of sampling site description resulted in the monitoring of areas representative of high selection pressure impossible[5]. Increased sampling of ‘‘hotspots’’ is required. The results of this simplistic study by just one applicant highlighted the shortcomings of the E.U legislation on GM crop cultivation in Member States.

Current E.U legislation, privileges and limitations

In the E.U legislation a safe-guard clause exists for Member States (MS). As a result of this clause countries may invoke to temporality restrict of prohibit use/sale of a particular GMO within their territory but must present justifiable reasons to demonstrate a risk to human health or the Environment [3]. The EC under its legislation is then required to investigate such reasons through the EFSA and pass judgement. The EC can request a country to withdraw its temporary restriction or in extreme cases take the case to court if the Member State is being uncooperative as under the E.U legislation, if the evidence presented by the Member States is unfounded, the ban must be lifted. The process of applying for this clause requires the following of a strict procedure. The Member States report on its opposing evidence must be submitted to the EC, the EC in turn distributes the report to other Member States for judgement. If the EC or Member States evaluate the risks proposed as genuine and scientifically backed-up, the EC must investigate through the EFSA’s GMO panel. If the argument is deemed unfounded, the EC can deny application for the clause. In relation to the Italian emergency measure, this clause was adopted without fully complying with the procedure outlined under article 34 of regulation (EC) No 1829/2003 [5]. The Italian government did not present a report to be distributed to Member States and the EC before the adoption of the decree of 2013, as a result under E.U legislation the decree is illegal [5].

Further limitations exist in E.U legislation in terms of the cultivation of GM crops. For example, co-existence is stated under legislation as being regulated through the use of buffer zones and isolation distances between GM and non-GM crops [3]. As part of this legislation, Member States are given the ability to impose different variations of the legislation which has resulted in inconsistency across Europe. For example in terms of co-existence, buffer zones differ from 15m in Sweden to 800m in Luxemburg[3]. Member States also have the ability to designate GM-free areas which effectively permits countries to ban GM crops in certain areas. In Italy, the regulating situation is complex consisting of patchwork binding rules and

administrative practices. Fragmentation and an unclear division of responsibilities between central government, local government and joint committees composed of regional and state representative's makes the debate of GM crops extremely difficult. Thus the lack of organisation in combination of Member States privileges when it comes to GM crop application has resulted in additional environmental risk assessments being introduced in different areas of Italy along with E.U directives which ultimately have made it impossible to conduct GM trials even if the ban is lifted [3]. This inconsistency and gaps in legislation surrounding application of GM crops throughout E.U Member States has resulted in uncertainty and distrust in the GM cultivation. Additional gaps in the legislation also exist in terms of laws surrounding new technologies in plant breeding. It is the view of the GMO scientific panel that questions exist in relation to the boundaries between GMO's and conventional breeding [3]. Continued advances in technology could give rise to these plant breeding products being defined as GMO under E.U legislation.

Conclusion & recommendations

To conclude, the argument proposed by the Italian government for the prohibition of maize MON 180 do not undermine the current legislation and defines the adopting of the 2013 decree before EC and Member State approval as illegal and must be retracted. In terms of the refunding of the GM famers who crops were destroyed and the differences between E.U and regional laws in Italy, the famers should be refunded by the Italian government as the adoption of the 2013 decree which resulted in the destruction of their crops was initially illegal as the procedure for applying for the emergency procedure was not followed. As a member of the GMO scientific panel for the EFSA, it is evident that the gaps between E.U and Member State legislation must be closed in order to improve the understanding of GM crops. In terms of the questions arising from advanced conventional breeding, new guidance is required or the existing guidance must be updated to include the advances in such conventional breeding. The EFSA environmental risk assessment also presents scope for greater harmonisation and more explicit guidelines in terms of GM cultivation practices for example. The increasing quality of PMEM's must be maintained and further developed. The main recommendation of the GMO panel is for the EFSA's guidelines on GM crop cultivation are accepted into legal text across all E.U Member States which will result in general consistency with the exception of different regional practices across Europe in terms removing the uncertainty of the issue.

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