# GMO-non coexistence in France: An analysis on the GMO coexistence report of the French High Council of Biotechnology

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### Introduction

In September 2010, the French competent authorities (Ministry of Food, Agriculture and Fisheries) sought the advice of the Scientific Committee of the High Council of Biotechnology, HCB(CS), on the question GMO coexistence. It requested a definition of the technical conditions relating to the cultivation, the harvesting, the storage and the transport of genetically modified plants with the objective of avoiding their accidental presence in other productions. The HCB(CS) took more than 1 year to formulate this advice. In general, the report follows a good scientific methodology and the conclusions are conservative. Many parts will be acceptable to most scientists working in the field of coexistence. For example, the report contains a good discussion on the horizontal transfer of transgenes (gene flow) for the 4 cultures studied (maize, soybean, potatoes and sugar beet). The report also considers the possible sources of fortuitous GMO presence in non-GMO cultures; a necessary step for defining the conditions necessary for coexistence. The HCB(CS) has also taken the necessary step of attempting to define the thresholds for the fortuitous presence of GMOs in non-GMO seeds; a necessary pre-requisite for coexistence since the level of GMO at harvest can never be less than the level in the seeds planted. It should be remembered that the European Commission has considered this problem for at least 10 years but without ever reaching a conclusion, due to political interference by the Member States.

In contrast, several important points are poorly treated and lack a scientific basis:

# 1) The values used as thresholds.

The threshold for the fortuitous and technically avoidable presence of GMOs used for labelling is 0.9% (Regulation 1829/2003). The HCB(CS) would have done better to issue a warning that this figure is arbitrary and was fixed by politicians for economic and psychological reasons. It does not have any scientific basis as was demonstrated by an editorial in Nature Biotechnology entitled "The numerology of idiocy" Nat. Biotechnol. 19 (2002) 319. This figure of 0.9% has become such a part of our everyday dogma that we have a tendency to forget its origin.

In Japan, based upon the same scientific data, the politicians decided on a 5% threshold; again not for scientific reasons but to please their bulk grain importers. Nonetheless, it is interesting to imagine that the EU could have avoided very many difficulties by following the Japanese example.

The same criticism of absence of a scientific basis may be applied to French labeling threshold of 0.1% for GMO-free products which will form the basis of a new French decree on GMO-free products (in preparation). This value was arbitrarily assigned by the French HCB Socio-economic and Ethical Committee based upon their own preconceptions and on the limit of quantification of the PCR methods available. Previous to this decision it was possible to imagine that GMO-free really meant GMO-free.

# 2) Units of Measurement for GMOs

As was noted in the introduction, the HCB(CS) report provides little in terms of innovation or imagination. One exception concerns the units of measurement of GMOs that they recommend for coexistence. The unit of measurement for GMOs has been the subject of many discussions (summarized in Davison et Bertheau 2007, CAB Reviews: Perspectives in Agriculture, (2007) Vol 2 N°007, 1-12; Davison, 2010, Plant Science 178 (2010) 94–98) and was finally defined as:

*GM* copy numbers should be expressed as the percentage, in relation to taxon-specific gene target DNA copy numbers, calculated in terms of haploid genome equivalent according to Recommendation (EC) 2004/787/.

This definition is normally known as the 'haploid genome equivalent' or HGE. Despite the numerous difficulties with this definition it has found general acceptance for the control of imports with the competent authorities of all EU member states due to its reliability across the entire food chain.

In its report, the HCB(CS) advises that the unit of GMO measurement should be changed to measure the relative presence of grains/roots/tubers calculated using a correction factor that takes into account the identity of the cultures in the neighborhood of the field being tested. The HCB(CS) considers that the objective is to measure the relative presence of GMOs in the grains/roots/tubers under investigation *irrespective of the nature of the genetic modification*. The HCB(CS) considers that a GMO is a GMO, irrespective of the nature and number of genetic modifications and that having multiple transgenic inserts does not make it more GMO than having a single insert.

While this last phrase may easily be understood for coexistence, it may be violently criticized by anti-GMO groups which wrongly confuse crop coexistence and food security. As correctly explained by the HCB(SC) the objective of coexistence is economic. Food safety is the role of EFSA, and without a positive evaluation from EFSA GMOs cannot be commercialized. However, and in contrast to the HCB(CS), for EFSA food safety evaluations GMOs with multiple inserts are considered very different and particularly so when the inserts are different as in the case of stacked GMOs.

Thus the report of the HCB(CS) suggests that the units of measurement must be changed to facilitate the cultivation of stacked GMOs which are on the increase in world agriculture. Stacked GMO in the USA may have as many as 8 GM inserts. If the HGE unit of measurement was used for such stacked GMO it would be virtually impossible to remain under the threshold of 0.9% (and still more impossible for 0.1%), without having dedicated production zones, as suggested in the EC Co-Extra project in 2009.

On the subject of units of measurement, one member of the HCB(CS) committee gave a divergent opinion, considering that the new HCB units would introduce a double standard between coexistence and the downstream food chains which would continue to use the EU HGE units. This double standard would not exist in other EU member states, which would also continue to use HGE units. This would leave France alone with its units base upon grains/roots/tubers and would lead to confusion and market disruption.

It is worth noting that this question was considered earlier under the EC Co-Extra project in 2008 in an article (not cited in the HCB(CS) reference list) devoted to stacked genes (Taverniers et al. (Environ. Biosafety Res. 7 (2008) 197–218 2009)) which proposed:

The haploid genome equivalent is proposed as the prevailing unit of measurement at all stages throughout the chain, in order to ensure that terminology and definitions of gene stacks are adapted to analytical detection, traceability, and compliance with EU regulations.

#### 3) Measurement uncertainty

The quantification of GMOs in (for example) a cargo, or a silo, is subject to measurement uncertainty. The HCB(CS) gives a good scientific account of the sources of measurement uncertainty (errors of irreproducibility between participating laboratories, sampling errors, etc) and notes that these may be enormous in comparison to the quantity of GMOs to be measured (*Macarthur, R., Feinberg, M., and Bertheau, Y. (2010). Construction of measurement uncertainty profiles for quantitative analysis of genetically modified organisms based on interlaboratory validation data. J AOAC Int 93, 1046-1056.)* However, despite this logical scientific discussion, the HCB(CS) then illogically decides that it will not take measurement uncertainty into account since it depend upon the choice of methodologies and the interpretation that are not related to the gratuitous presence.

Obviously since measurement uncertainties accompany all scientific measurements, only an analysis of measurement uncertainty can determine whether the results are scientifically valid. Thus the suggestion of the HCB(CS) would fail to distinguish false positives and false negatives. This attitude is unexpected for an independent scientific council, acting without political interference.

### Conclusions

The report of the HCB(CS) obeys a specific request from the competent authorities and thus cannot be directly criticized for considering the EC labeling threshold of 0.9% and the French GMO-free threshold of 0.1%. However, it was the duty of the HCB(CS), as a scientific committee, to remind the competent authorities that these thresholds are simply the products of political imagination and have no scientific value. The values could be changed.

The HCB(CS) proposed to introduce a new system of GMO measurement that will be used only in France and only for coexistence. The rest of Europe, as well as all commerce in France, will continue to use the EC standard HGE units. The introduction of a dual measurement system would create many problems for food and feed supply chain coexistence.

The HCB(CS) proposes to totally ignore measurement uncertainty in GMO quantification. It should be remembered that the measurement uncertainties are very large compared to the values of GMOs being measured. It is futile to attempt to quantify GMOs unless an analysis of measurement uncertainty is performed.

Finally, it is necessary to ask why the competent authorities have asked the HCB(CS) for a report on this subject, despite the fact that the answers are already known; namely that coexistence is possible for the EC threshold of 0.9% (using defined precautions already in use in the coexistence regulations of other EU member states), but difficult (impossible?) with the French GMO-free threshold of 0.1%.

To understand this, it is necessary to remember several facts:

1) GMOs have not been cultivated in France since February 2008 and the government has repeatedly, and also very recently, declared that the moratorium will continue. Thus there is no coexistence in France and there will be no coexistence in France and there is no need for either a HCB(CS) report nor coexistence regulations.

2) The French GMO moratorium is illegal under French law (French State Council, January 2011), under European law (European Court of Justice, September 2010) and under international law World Trade Organization). France has thus placed itself in a position of an outlaw state in respect to GMOs

3) France has invoked a safeguard clause to justify the 2008 moratorium. This safeguard clause has been rejected by the European Court of Justice and by EFSA. To justify its moratorium France must now find a new and, this time, scientifically-based, safeguard clause.

Thus it seems likely that the request from the competent authorities to the HCB(CS) is an attempt to find a scientific base for a new safeguard clause and perhaps profit from the new EC recommendations that may permit GMO-free zones over a large part of the territory.

Consequently, if (i) the HCB(CS) advises the competent authorities that a threshold of 0.1% GMO is impossible (as it has now done) (ii) the French government publishes the decree (in preparation), specifying a GMO-free threshold of 0.1%, then (iii) the cultivation of GMOs will be incompatible with the new GMO-free decree and, at last, the French government will have a valid scientific reason to maintain the moratorium and make the entire of France GMO-free. Naturally, in such a scenario, the HCB(CS) will lose all pretence of independence and scientific credibility, and will be seen as a simple instrument to support the political will of the of the French government.