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Coexistence - The Missing Link in the EU Legislative Framework

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Ladies and Gentlemen,

In view of the title of my presentation here this morning, which refers to coexistence as the "missing link" in the EU's regulatory framework for agricultural biotechnology, I have mixed feelings about the previous presentation made by Mr. Bianchi, on behalf of the European Commission.

On the one hand, if he were to have used this opportunity to announce a major reconsideration of the Commission's persisting refusal to regulate coexistence at EU level, there would be no more "missing link" for me to discuss. However, in fact, I am glad to hear Mr. Bianchi acknowledging that coexistence is, or was, a "missing element" in the framework.

On the other hand, I would have warmly welcomed such a reconsideration, as I believe that the EU-level is the most appropriate level at which to tackle the difficult issue of coexistence. I realize that this may not be an altogether popular position at this GMO-free *regions* conference, but I think the arguments supporting this position are sound, and I will ask you to bear with me. In this rather brief presentation, I will focus on the *level* for regulatory action, rather than the finer legal intricacies involved, due to time constraints.

Many of the other presenters here today, and tomorrow, will talk about ways to prevent or restrict GM crop cultivation in the EU altogether. To avoid duplication, I will instead treat GMO cultivation as an imminent political reality, and discuss at what level its coexistence with existing farming practices might best be organized from a legal perspective.

Harmonization of coexistence policies and rules would be consistent with the overall approach to the regulation of agricultural biotechnology which the EU has followed to date. Throughout the past two decades, there has been a clear trend of increasing harmonization on GMO-issues, both in substantive and in procedural terms, with the increased pre-emption of national autonomy, and with the shift from the Directive to the Regulation as the legislative instrument of choice.

But with respect to coexistence, this steady trend has now been broken. After having rather exhaustively harmonized the initial and final stages of the GMO-product cycle, that is the authorization and the distribution stages, the Commission has decided to leave a regulatory gap in the intermediate stage, which involves the farm-level cultivation of GM crops.

The Commission's approach to fill this regulatory gap at the national level, based on the principle of subsidiarity, appears both unconvincingly argued as well as

incompatible with the efficacy and perhaps ultimately even the viability of the overall regulatory regime for agricultural biotechnology. Hence, it appears an equally unsatisfactory and inadequate regulatory approach on both sides of the divisive "GMO-fence".

Briefly regarding the flawed arguments. Essentially, in the 2003 Coexistence Guidelines Recommendation, the Commission argued that local diversity in, for example, climatic and agronomic conditions rule out uniform coexistence rules. While this may, at least to a certain extent, be true for technical growing conditions and certain Good Farming Practices, it does not appear to provide any sound argument against harmonized EU-level rules on, *inter alia*, liability and redress schemes, cross-border issues, harvest- and post-harvest supply chain segregation or identity preservation schemes, specific purity standards for seeds and organic produce, contingency plans, etc.

Furthermore, briefly on the threat which this subsidiarity-based approach to coexistence forms for the effectiveness and viability of the current regulatory regime, which presumably must be the ultimate objective of the Commission. The regime foresees in highly harmonized rules and standards in the authorization and distribution stages of the GMO-product cycle, including post-introduction risk-management, labelling, and product-traceability requirements. The functionality and efficacy of these norms largely depends on the ability to identify and to locate GMO materials throughout the product supply chain. Difficulties are likely to emerge in this regard at the input (or cultivation) stage, if highly divergent national coexistence regimes are adopted in the various Member States, which defy this crucial uniformity.

But the lack of uniform coexistence rules also undermines the legal meaning of some of the key concepts of the current legislative regime. The quintessential example is perhaps the concept of "adventitious presence", as the criterion for the labelling exemption under 0.9% GMO content. For a successful invocation of this exemption, operators/farmers must prove that they have taken "appropriate preventive measures" and that the GMO presence was truly unintended and technically unavoidable. However, ironically, such measures (Good Farming Practices) are not defined anywhere in the current regulations. If this crucial criterion of "appropriate preventive measures" is to be defined differently in each Member State, as the Commission's approach implies, this will likely create serious challenges and render the adventitious presence rule difficult to enforce. This rule and these concepts are also crucial for the determination of liability and/or compensation claims, both from a claimants as well as from a defendants perspective in cases involving GMO admixture/contamination.

Such challenges will be of particular prevalence and relevance in cross-border regions, where it will be difficult to determine which set of national rules should apply to a given case, and where farmers will effectively have to comply with various regimes simultaneously.

The likelihood of substantial discrepancies between national systems is significant, given the political status quo of disagreement on GMO-issues. In fact, such discrepancies have already begun to show in the first national (draft) coexistence policies.

It is interesting to note that, although the Commission's *de jure* position remains that harmonization is neither necessary nor viable, *de facto* it appears to be eager to exert a significant level of control, in other words to harmonize "through the

backdoor", by testing Member States' draft laws against its own non-binding coexistence Guidelines as an authoritative benchma rk in the TRIS procedure.

Although this would appear to be an acknowledgment of the need for uniformity, this undemocratic legal scrutiny procedure on the basis of *non-binding* opinions of the Commission, is neither a legitimate nor an effective alternative to proper harmonization, involving also the European Parliament and the Council (plus, one would hope, stakeholders).

This observation is not affected by the Commission's very recent initiative, of just last week, to establish a Coexistence Bureau within its JRC in Seville, to draw up – once again – non-binding crop-specific technical growing guidelines.

Another important reason why using the Commission's Guidelines as a benchmark for national laws is problematic, is that they illegitimately restrict the Member States' autonomy to require strict non-GMO purity levels.

The use, or rather abuse, of the 0.9% figure of the purity labelling rule as a *minimum regulatory target* below which Member States cannot legislate, is quite clearly not consistent with the intended nature of this purity rule as a *maximum tolerable* impurity *threshold*, which furthermore was conditional on being adventitious or technically unavoidable, and hence could never be used as an intended *target*.

Somewhat surprisingly perhaps, given t he usual division and disagreement on GMO-matters, it is not just the Commission who has hailed the subsidiarity-based approach to coexistence, but also for example parts of the GMO free regions movement, who are eager to retain flexibility for more precau tionary regional measures.

However, I would like to emphasize that the level of harmonization which I propose would be a baseline-minimum, while still allowing for certain flexibility in terms of zoning and local growing conditions, for example. For liabi lity and segregation and identity preservation schemes, cross-border issues, contingency plans, etc., there is much less, if any, need for such flexibility.

Baseline harmonized standards of this kind, drawn up in cooperation with the critical European Par liament, and lending an ear to stakeholders, would provide the necessary basic safeguards for the event that GM cultivation in Europe does indeed become a reality and if the pressures and restrictions on Member States' precautionary measures were continue.

While it would certainly be naïve to suggest that the negotiation and adoption of harmonized baseline coexistence (including liability) rules would be an easy task given the persisting deep political divide on GMO-issues, this should not *a priori* be a reason to disregard the requirements of legitimacy, consistency, and coherence in lawmaking, as vital elements of the Better Regulation and Good Governance agendas to which the Commission has firmly committed itself.

A re-evaluation of the current EU app roach to coexistence is due by 2008, following the May 2006 Council conclusions, but it is to be hoped that the Commission will bring proposals before then, since as the number and the diversity of national coexistence regimes is growing, it will be ever m ore difficult to revert to a harmonized policy. Meanwhile, the Commission's argument that a re-evaluation of the need for harmonization should be put off until further experiences have been

gained appears rather forced, given that such experiences are not likely to be gained any time soon, as a surge in the uptake of GM crops for cultivation is highly unlikely in most Member States for the moment.

Moreover, a timely re-evaluation of the EU coexistence policy is also advised in view of the imminent new challenges posed by next-generation GM crops with novel applications aimed at, for example, bio-pharming, biofuels, and industrials.

Coexistence is by its very nature a *Community* issue, in the context of EU-wide authorizations for GMO introductions, and the free circulation of GMO products throughout the Community internal market.

In conclusion, it is crucial that coexistence policy, as the missing link in the EU legislative framework, is devised not in *isolation* from but in the *context* of and *consistent* and *coherent* with the already existing regulatory instruments on agricultural biotechnology.

In the absence of an EU-level approach to coexistence, there appears little hope for the practical and political viability of the EU regime for GMOs , including those safeguards which it provides, meaning that even a recurrence of the political and legal crisis of a decade ago may once again be looming. While this prospect might seem appealing at first sight to some members of the GMO free regions here today, I would propose that such an uncertain and unstable outcome would not be to anyone's gain, at either side of the fence, in particular if the regulatory framework collapses while the contested GM seeds have already been introduced to the European soils.

Ultimately, the European farmers, consumers, and the environment, stand to pay the price for an inconsistent and ineffective legal approach to coexistence. I believe that this should be avoided at all cost.

Thank you.

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