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Coexistence - The Missing Link in the EU Legislative Framework Subsidiarity vs. Harmonization on the Final Frontier of the EU Regulatory Regime for Agricultural Biotechnology

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In contrast to the whirlwind pace and the efficiency with which the science and commercialization of modern biotechnology have developed in the past few decades, the creation of an adequate and comprehensive regulatory regime for agricultural biotechnology has proven to be a lengthy and arduous affair.

The EU's troubled experience with the regulation of 'green' biotechnology in the agricultural and food production sectors is, in many respects, the quintessential example of these difficulties. Complexities of, *inter alia*, persistent political deadlock among Member States as well as EU institutions, fierce public opposition, and a struggling global competitiveness position, have frustrated the EU regulatory efforts since their inception.

Following the disintegration of the initial EU legal framework, in the 1990s, a major revision has been undertaken in recent years. By 2004, the European Commission declared the overhaul of the regulatory regime complete, and effectively lifted the longstanding *de facto* moratorium on authorization of imports of GMOs. Moreover, it has resumed the authorization process for the EU-wide cultivation of GM crops, in the face of unrelenting deep political divide between the Member States.

With this re-opening of the floodgates to Europe's internal market to GMO-imports, and with the imminent commercial-scale cultivation of GM-crops on EU soil, the regulatory regime will be put to the test once again. The pressing question which emerges is thus whether, this time around, the revised regime will indeed prove complete and adequate, and whether a repeat of events leading to the political stalemate of the 1990s can be avoided.

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However, it is here submitted that, contrary to the Commission's conviction, the EU regulatory regime is *not* yet complete, and that the lack of a consistent, coherent, and integral regulatory approach threatens to undermine the effectiveness of, or even make redundant, the legislation that has so far been put into place. Serious omissions can be identified in the arsenal of regulatory instruments and the definition of pivotal legal concepts, with the ultimate potential to paralyze the entire framework, once again.

The most vital missing link is to be found at the very heart of the regulatory and production cycles of GMO commodities, namely in cultivation stage. The now impending large-scale uptake of GM crops for cultivation within the EU has added a new, and potentially complicating, dimension compared to the situation of one decade ago. Central to this new dimension is what has become known as the 'coexistence debate', essentially referring to discussions about the need for (as well as nature and scope of) regulatory measures to ensure that the introduction of agricultural biotechnology will not mark the end of established non-GMO practices of 'conventional' and organic farming, and various identity-preserved crops. Instead, the Commission's formal ambition is to have all types of agriculture 'peacefully coexist', and to enable farmers (and by proxy consumers) 'to make a practical choice between conventional, organic and GM-crop production, in compliance with the legal obligations for labelling and/or purity standards.'

Applications of biotechnology span across all stages of the product cycle of agricultural biotechnology commodities, that is, from GM seedling to final (consumer) product. From an EU regulatory perspective, three major stages can be identified in the (simplified) product cycle of such GMO commodities: (i) authorization, (ii) cultivation, and finally, (iii) distribution. It would appear evident that any legal regime with the objective of regulating this technology should equally span across this entire product cycle. However, an analysis of the past and present laws and policies on agricultural biotechnology demonstrates that the EU regime has, throughout the past two decades, not succeeded in meeting this objective.

In the EU, the body of law and policy on (agricultural) biotechnology has been gradually expanding since the adoption of the first framework legislative acts in 1990. However, this expansion has occurred in a rather piecemeal fashion, lacking an overall or integral strategic approach. The result has been a patchwork of laws, requiring continuous updating and revision, both to fill loopholes and to catch up with the non-stop, quantum leap developments in molecular science.

Throughout the past two decades, the regulatory efforts have been principally aimed at regulating the *first* and *final* stages of this cycle, i.e. the authorization and the distribution stages. The focus has been on prescribing *ex ante* (i.e. prior) scientific safety assessment and regulatory authorization as a precondition for contained or environmental releases of GMOs, in addition to post-introduction risk management controls including monitoring and registration requirements, as well as transparency and consumer 'right-to-know' labelling and registration measures and product tracing provisions. This concentration on the completion and fine-tuning of the regulations in the *initial* authorization and *final* distribution stages of the product cycle has been much to the exclusion of the *intermediate* cultivation stage, which has been left largely un- or under-regulated at EU level. It is therefore evident that a regulatory gap has been left in this rather crucial intermediate stage, involving the thorny issue of coexistence of GMO and non-GMO farming. The anomaly created by this regulatory

gap is that a regime which allows for the authorization of GMOs for cultivation, and which sets qualitative end-of-cycle targets and requirements for the final cultivated products, but which fails to provide any substantive prescriptions for how the cultivation itself should be operationalized in practice.

The Commission has clearly indicated, in its Recommendation 2003/556/EC on Guidelines for the Development of National Strategies and Best Practices to Ensure the Coexistence of Genetically Modified Crops with Conventional and Organic Farming (Coexistence Guidelines), that it does not intend to fill this regulatory gap with harmonized coexistence regulations. Instead, it has stated a preference for a subsidiarity-based approach, leaving it up to each of the Member States to devise national or even regional coexistence policies, citing as arguments the diversity in, *inter alia*, the agronomic and climatic conditions throughout the EU. Moreover, in declining to propose EU-wide coexistence-specific liability rules, the Commission has argued that civil liability is not within its mandate (although this would appear to contradict its previous positions on this issue taken in the context of the deliberations with the European Parliament and the Council on the revised Deliberate Release Directive and the Environmental Liability Directive).

At the same time, although the Commission's formal position on coexistence is that harmonization is neither necessary nor viable, it does appear eager to exert some level of control over Member States' coexistence regulations, by testing these against the benchmark of its own *non-binding* Guidelines in the Directive 98/34/EC Technical Regulations Information System (TRIS) procedure. Since national coexistence measures constitute technical product regulations, and as such have the potential to distort internal market trade, they must be notified in draft form prior to being adopted in national law, and lacking this cannot be enforced or invoked before national courts. In addition, whereas the establishment of the Coexistence Network Group (COEX-NET), in 2005, could be argued to imply an acknowledgment of the need for synchronization and consistency of national coexistence systems, the Commission has stressed explicitly that this group is not intended to develop a harmonized approach or to scrutinize individual measures, but rather to 'provide an expert forum for sharing experiences and information between Member States on results of scientific studies and best practices for national coexistence strategies'.

It is worth noting that prior to the coexistence debate, a trend could be observed whereby the EU actually shifted from a brief initial period of relatively minimal harmonization (creating a regulatory 'floor', rather than a regulatory 'ceiling'), to increasingly exhaustive harmonization, with almost complete pre-emptive effect on national regulation. The same trend is also noticeable in procedural terms, as the regulatory instrument of choice in the area of biotechnology has shifted from (framework) Directives to Regulations.

Despite repeated, argued calls from a variety of stakeholders including civil society organizations, several Member States, as well as the European Parliament, the European Economic and Social Committee, and the Committee of the Regions, the Commission has maintained its subsidiarity-based approach to coexistence to date, arguing in its March 2006 evaluation report that the limited experiences with Member States systems do not allow for an adequate consideration of the need for a harmonized approach at this time. Neither the outcome of the April 2006 Vienna stakeholder conference on coexistence jointly organized by the Commission and the

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Austrian Council Presidency, nor the May 2006 Council conclusions – which included an invitation for the Commission to explore the option of some level of harmonization on coexistence – inspired the Commission to reconsider its approach.

Although the Commission's most recent mid-term review of the EU Strategy on Life Sciences and Biotechnology (April 2007 – Action 17) does refer to both this conference and these Council conclusions, as well as emerging pressing coexistence issues, no specific actions have yet been proposed.

In the meantime, an increasing number of Member States is adopting national coexistence policies and laws, with sometimes highly diverging standards and prescriptions. In view of the persisting, seemingly unbridgeable political divide between the various Member States, it is hardly surprising that substantial discrepancies will exist, with all inherent problems, also from an internal market and legal certainty perspective. These differences relate not only to the technical growing conditions, and 'Good Farming Practices', including isolation distances between GMO and non-GMO crop plantings, but also to liability and compensation schemes, segregation of supply chains, and information and transparency requirements. Such discrepancies between national systems will pose particular problems in the many cross-border regions which are characteristic for Europe.

What is more, arguably, as the number as well as the diversity of national coexistence systems increases, it will be increasingly difficult to revert to a harmonized policy in the future, if and when the EU legislature might acknowledge the need for this.

Moreover, the discrepancy between EU-wide harmonized standards and norms in the authorization and distribution stages, and the highly diverging Member State regulations in the intermediate cultivation, or coexistence, stage, forms a serious threat to the functionality and efficacy of the overall regulatory regime. If all GMO products were produced in contained environments, such as laboratories or secured greenhouses, the current regulatory safeguards for GMOs (including post-introduction risk management measures and identification, labelling, and product tracing systems) might work perfectly, as there would be little or no possibility for the GMO crops to be mixed with, or to interact with, other (non-GMO) crops or other elements of their surrounding environment. However, the reality of farming is that it occurs in an open-environment setting, without physical containment features. Therefore, in the everyday reality of farming, it will be extremely difficult, if not impossible, to avoid some level of commingling or admixture, or 'contamination', to use a less neutral term. In the absence of harmonized substantive guidelines on how to avoid such admixtures, these efficacy and functionality of these existing regulatory measures may be greatly diminished, or at least complicated.

Moreover, the lack of harmonized coexistence provisions also threatens to deprive some of the key concepts of the existing regulatory regime of their legal and practical meaning, making them downright unenforceable and, ultimately, redundant. Perhaps the most striking example of this is the notion of 'adventitious or technically unavoidable presence' of GMO material in the non-GMO product flow. Adventitious presence is a pivotal concept in the current EU regulatory regime as it is the determining factor for the application of *de minimis* purity thresholds, below which the GMO labeling requirements may be waived for otherwise non-GMO products, despite the trace-presence of transgenic material. In addition to setting a numerical purity thresholds (at 0.9%) the current regulations also make the invocation of a

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labeling-waiver dependent on the operator/farmer's ability to demonstrate that 'appropriate preventive measures' were taken to avoid the adventitious presence. Evidently, such 'appropriate preventive measures' boil down to Good Farming Practices, as part of a coexistence policy. Ironically, the current regulatory regime does not define such measures. This example clearly demonstrates how the practical application of the current regime hinges in large part on uniform, unambiguously defined segregation strategies, seed purity standards, and best practices for farmers and other operators – that is *coexistence policy*, but no such policy has yet been adopted at EU-level. In view of the Commission's repeatedly confirmed approach to the regulation of coexistence, such EU-wide definitions and standards are not to be expected in the near future. Although there are indications that the Commission is developing guidelines for crop-specific technical measures for coexistence, these are not likely to be completed for some time, and they will most likely take the form of a non-binding Recommendation, making their legal status in the context of a disputed labelling waiver uncertain.

All of these challenges and complexities will only be compounded by the ongoing advances in the science of agricultural biotechnology, as new generation GMO-crops and novel applications for their ingredients continue to emerge. This includes the growing focus on pharmaceutical crops, biofuels, industrials, and other non-food/feed applications of GM crops, as well as the increasing use of gene stacking in GMOs.

Hence, as a consequence of the lack of harmonized policy for this vital coexistence stage, the current regulatory regime is flawed at its core – reduced to a proverbial tree without roots, which as such is doomed to suffer from fatal instability. In fact, it is not inconceivable that it may ultimately set the stage for the downfall of yet another generation of the EU regulatory regime for agricultural biotechnology.

For these reasons, the Commission's preferred subsidiarity-based approach to coexistence appears incompatible both with the efficacy and even viability of the current EU regulatory regime for agricultural biotechnology (including health and environment concerns, in addition to economic issues), as well as with the proper functioning of the EU internal market. The objective of creating a comprehensive and stable regulatory regime aimed at preserving the proper functioning of the internal market and enhancing the EU's competitiveness in the global biotechnology industry, while at the same time ensuring a high level of protection of human health and the environment, will be impossible to meet without a thorough reconsideration of the Commission's current coexistence strategy.

It is crucial that a coexistence policy be devised not in isolation from, but in the context of and consistent with the regulatory instruments already in place for agricultural biotechnology. Particularly in view of persisting political divide, a certain level of (minimum) harmonization appears imperative, and the Commission's arguments against such an approach appear rather unconvincing. Without EU-wide baseline technical norms for coexistence and segregated supply chains, as well as harmonized liability and compensation rules, there appears to be little hope for the practical and political viability of the regulatory regime for agricultural biotechnology as it has been painstakingly revised in recent years. Only through the adoption of an *integral* (spanning the entire production cycle), and internally consistent and coherent *Community* regulatory regime will the EU be in a position to avert a recurrence of the political and legal crisis of the late 1990s.