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Europe**

Notes on the Commission's proposal to create Multi-National Authorisation zones under COM (2006) 338

Arbitrary, and based on politics, not similarities

The Commission's proposal to amalgamate Member States into three multi-national authorisation zones (Map 1) has no actual basis in terms of agricultural, plant health, and environmental (including climatic) similarities as suggested in Article 3. The authorisation groupings proposed are arbitrary, and bare little resemblance to various scientific attempts at dividing Europe into eco-climatic zones. The Habitats Directive, for example, recognises 9 different bio-geographical regions within the EU; few of which are arranged in accordance with national borders (see Map 2). While the European and Mediterranean Plant Protection Organisation's (EPPO) recent attempt at identifying regions of 'comparable climate' with regards to pesticide authorisations concluded that Sweden and Denmark should be grouped with Germany; Eastern Europe should be a zone in itself; the northern half of France should be grouped with Benelux; and four zones should be created in total – a radically different arrangement to that proposed by the Commission (see Map 3). The Commission's proposed multi-national zones are further undermined by high resolution assessments of European climatic variation made using satellite-based remote sensing technology which show the EU to be a dynamic mosaic of microclimates¹ (see Map 4): not a small number of discrete climatic blocks aligned according to 20th century political boundaries.

Inadequate accommodation of local conditions

The Commission's proposed Regulation includes provision for Member States to amend authorisations accepted on the basis of mutual recognition by adding additional restrictions designed to better protect agricultural workers and rural residents (Art 30 & 40). However, given the Commission's belief that the three multi-national authorisation zones delineated in Article 3 represent regions of agricultural, environmental and climatic similarity, the draft text contains no equivalent provision enabling Member States to impose restrictions on the basis of agricultural, environmental, or climatic variations. Furthermore no provision is made for other factors, such as ground water sensitivity in the cases of Denmark and Eastern European counties, to be taken into account. Given that the proposed zones are not based on climatic or environmental equivalence, and that other factors such as water treatment facilities are also highly variable within each zone, the absence of such provisions is deeply problematic.

¹ Personal Communication with Dr Jürgen Born, Spatial Business Intelligence GmbH, 16 January 2008

Multi-stakeholder consensus against zones

The rejection of the Commission's proposal to create multi-national authorisation zones, and to introduce 'obligatory mutual zonal recognition', was supported at the Parliamentary level by Hiltrud Breyer MEP, Parliamentary Rapporteur on the proposed pesticide Regulation, the European Parliamentary Environment Committee, the European Parliament, the European Crop Protection Agency² (ECPA), and Pesticide Action Network Europe (PAN Europe). In advising Members of the European Parliament (MEPs) on the Commission's proposals, ECPA warned MEPs that, 'Mutual recognition should give Member States the opportunity to take specific climate and agricultural conditions into account', and urged MEPs to support amendments rejecting the creation of authorisation zones.

Reducing administration by other means

While it is essential to maintain the highest standards in protecting human health and the environment, it is reasonable to reduce the administrative burden of the pesticide authorisation process wherever this can be achieved without compromising the extent to which decisions on pesticide authorisations take local circumstances into account. We note that:

- The administrative process has recently been simplified by the harmonisation of some Maximum Residue Limits (MRLs) within the EU food chain, thus eliminating the need for additional field trials to accommodate national variations in MRLs. Further gains will be made in the coming months when harmonised MRLs are established for all other pesticide substances.
- In its proposed Regulation the Commission sets out detailed guidelines by which substances should be evaluated for authorisation including the establishment of 'uniform principles for evaluation and authorisation' (Art 29: 6) incorporating the requirements of Directive 91/414 and leaving provision for necessary modifications: a measure which will further reduce the complexities of the authorisation procedure.
- Additional guidelines relating to the authorisation process have already been widely adopted with regard to judgements relating to risk assessment for birds, mammals, the aquatic environment, and groundwater pollution, thus further reducing the incidence of field trial replication.
- Recent advances in satellite-based remote sensing technology allow the identification of geographically separated sites which share similar climatic and soil characteristics³. Such technology holds the potential to enable greater transferability of field trial results from one Member State to another – thus further reducing administration relating to pesticide authorisation.

Why follow the lowest common denominator?

The principle of 'obligatory mutual zonal recognition' is inherently geared towards the position of the lowest common denominator, thus making it an undesirable tool with which to promote greater harmonisation between zones. Every pesticide will gain authorisation within a zone except for those substances denied authorisation by all Member States. The Council should instead investigate the possibility of promoting greater uniformity around the highest common denominator by

² 'Regulation concerning the placing of plant protection products on the market (COM 2006/388): Evaluation of amendments proposed by the Environment Committee', European Crop Protection Agency. (Available for download at www.ecpa.be)

³ Spatial Business Integration GmbH http://www.spatial-business-integration.com/SBI/content/e1324/e1345/e1361/e1362/e1363/Flyer_SSC_SBI_06.pdf

encouraging Member States to revoke the authorisation of any pesticide rejected by another member of the European Union.

The advantage of autonomy

The reinforcement of the principle of mutual recognition within the context of authorisation zones, eliminates the capacity of individual Member States to go beyond the position of the lowest common denominator in making decisions regarding product licensing. This fundamentally jeopardises the creation of National Action Plans as envisaged by the Framework Directive on the Sustainable Use of Pesticides, and would leave Member States powerless to address specific local issues other than those relating to human health or agricultural workers and rural residents. Denmark, for example, would be unable to impose specific unilateral restrictions designed to accommodate its acute groundwater pollution sensitivity, while President Sarkozy's recent decision, following a 3 month multi-stakeholder engagement initiative, to withdraw 53 of France's most hazardous pesticides would have been impossible.

A stepping stone towards a 'fully centralised system'

The amalgamation of Member States into three multi-national authorisation zones represents a stepping stone towards the total abandonment of authorisation assessments conducted at the Member State level. In its summary of responses to consultations held in parallel with the drafting of the proposed Regulation, the Commission notes support among certain stakeholders for a 'fully centralised authorisation system' (Explanatory Memorandum). This notion won support among a minority of European Parliamentarians with one MEP proposing an amendment such that: 'Dividing Member States into authorisation zones is regarded as the first step towards establishing an integrated internal market for plant protection products on which authorisation of a plant protection product is valid throughout the EU'.⁴

A 'race to the bottom'

The Commission anticipates that national authorities responsible for assessing pesticide authorisations will be financed, at least in part, by levies on corporations applying to put pesticides onto the market (Rec 43). This expectation is not controversial. Many national authorities are already reliant on fees charged to industry: the UK PSD, for example, recovers some 60% of its total operational costs in this way (€1.25 million per annum)⁵. The Commission also makes provision for corporations to select which national authorities are responsible for conducting assessments of their pesticide authorisation applications (Art 32: 2b & Art 34). Furthermore, in reinforcing the principle of 'mutual recognition' (Art 40), the Commission eliminates the economic security each authority gains from acting as the exclusive gatekeeper to a given territory; instead establishing multiple gatekeepers for every zone. The Commission thus creates conditions which strongly incentivise a 'race to the bottom'. National authorities with strong track records of serving precautionary judgements will be bypassed as the more pro-industry authorities quickly come to dominate the market. Incremental erosion of environmental and human health considerations will be rewarded. Any tendency towards stricter judgements will be strongly disincentivised.

⁴ Amendment 178 proposed to ENVI Committee by Richard Seeber MEP (Austria, EPP), 11 September 2007

⁵ Better Regulation, Compliance and Enforcement Strategy, Pesticides Safety Directorate (September 2007) http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/Pesticides_Forum/PF160.pdf

Pesticide authorisation in the USA

While the Commission appears to consider the current degree of autonomy afforded to the EU's 27 Member States as creating an unnecessary administrative burden, no such consideration is witnessed in the USA, where all 50 American states retain the full right to make independent authorisation assessments of pesticides approved at the federal level. The comparison between the US and EU is made more relevant by the equivalence in the range of sizes of American and European states. The largest US state is Texas, which is about the size of France; the smallest is Rhode Island, which is about the size of Luxembourg.

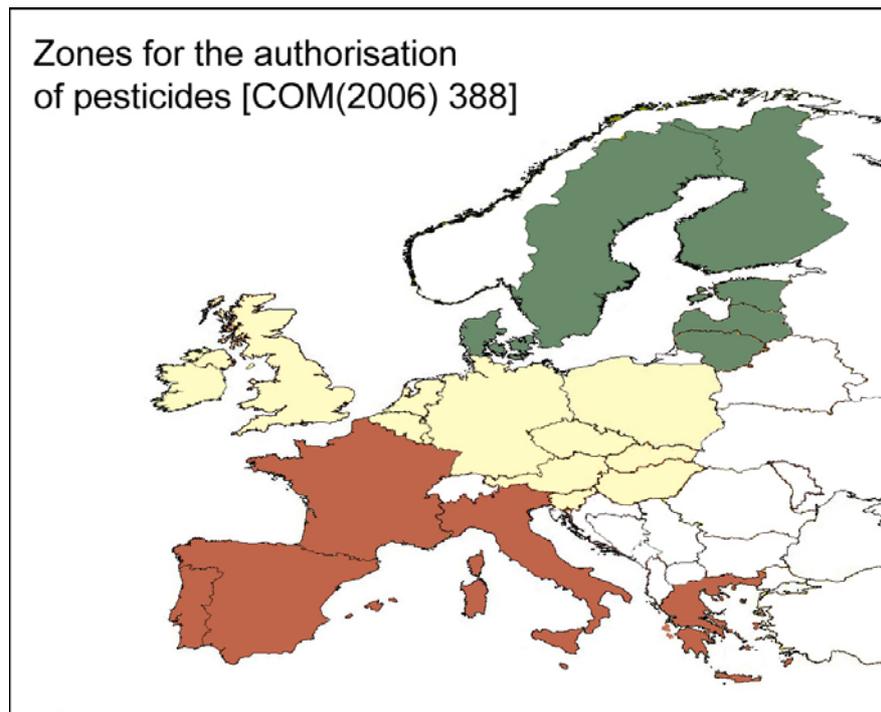
No benefit to human health or the environment

While the Commission states that 'the purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment' (Rec 8), the only stated advantages of the proposed system of 'obligatory zonal mutual recognition' are 'to avoid any duplication of work, to reduce the administrative burden for industry and for Member States and to ensure a more harmonised availability of plant protection products' (Rec 24). At no point in the proposed Regulation does the Commission refer to any environmental or human health benefits derived from creation of zones or the reinforcement of the principle of mutual recognition.

No exemption for greenhouses

In cases where authorisation is granted for use in greenhouses or as a post-harvest treatment the Commission proposes that the principle of obligatory mutual recognition be extended to encompass the whole of the European Union (Art 39). This proposition takes no account of the variability in agronomic practices across the EU. In many Mediterranean countries, for example, green house cultivation and post harvest treatment practices are far less rigorous. Thus pesticides used under these scenarios have the potential to impact far beyond the confines of the agricultural buildings in which they are applied.

Map 1: The three multi-national pesticide authorisation zones proposed by the Commission in its draft Regulation: COM (2006/388)

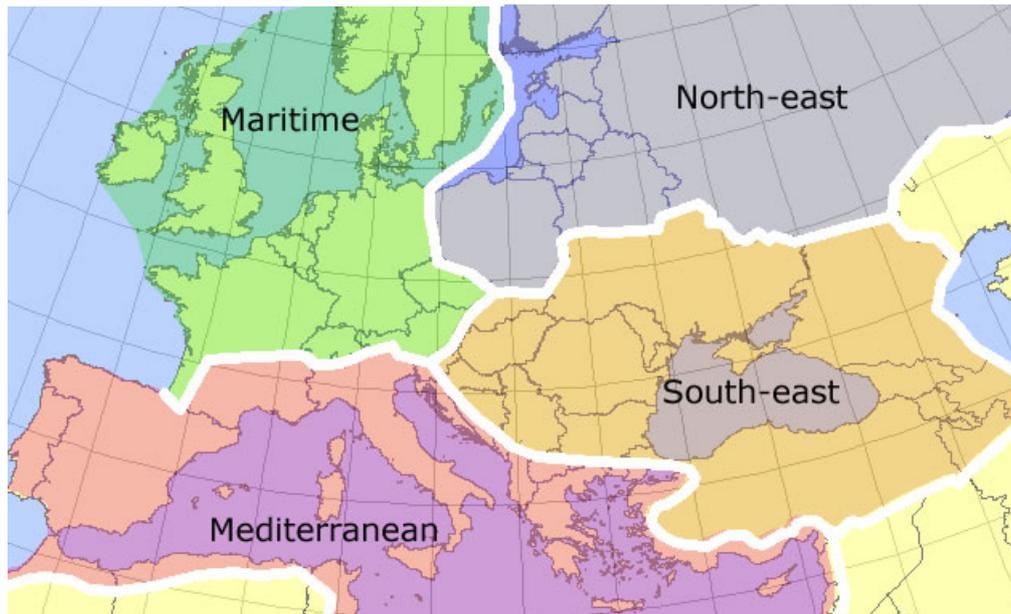


Map 2: The nine different bio-geographical zones officially recognised by the Community under the Habitats Directive (92/43/EEC)



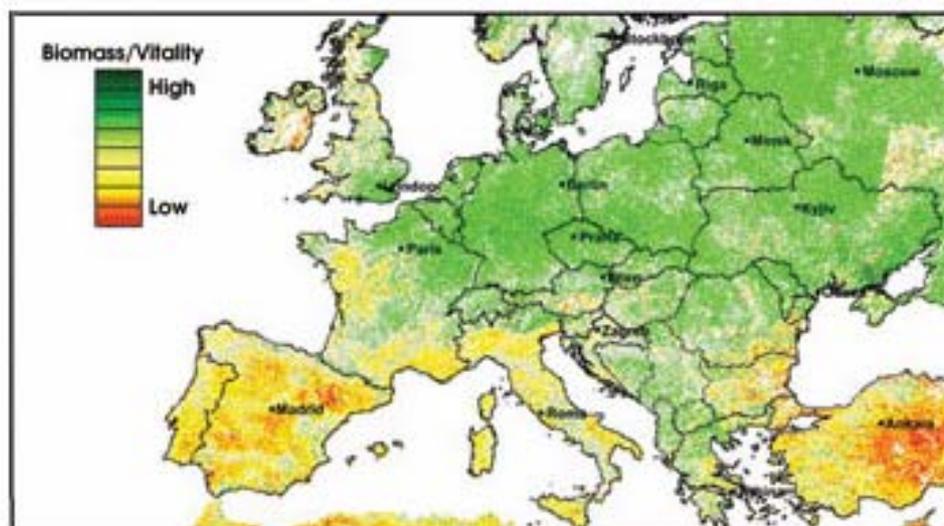
<http://dataservice.eea.europa.eu/atlas/viewdata/viewpub.asp?id=221>

Map 3: The four ‘Comparable Agro-Climate Zones’ according to EPPO (2005)



http://www.eppo.org/PPPRODUCTS/ppp_standards/comparable_climates.htm

Map 4: The mosaic of microclimates identified using satellite-based remote sensing technology (Spatial Business Integration GmbH)



www.spatial-business-integration.com