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Shutting the stable door after the horse has bolted? Risk assessment and regulation for transgenic forages

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Introduction The regulation of GM agriculture in Europe is a matter of considerable public interest. The development of a regulatory framework has imposed significant additional costs without generating broad public acceptance. However, the current risk assessment and management framework does provide a basis for considering how the broader issues surrounding the introduction of any novel agricultural technology might be approached.

The Status Quo The regulations are administered EU-wide on a case-by-case basis and are based upon an assessment of the likelihood of the release causing harm to human health and the environment. Consents to release into the food chain are time-limited, revocable and require a programme of post-market monitoring to validate the original risk assessment. Regulatory approval also involves an assessment of the wider impacts of changed agricultural practices associated with a GM crop release. The farm-scale trials of GMHT crops showed that use of broad-spectrum herbicides for weed control impacted on the non-agricultural food chain in a highly crop-dependent manner, with conventional crops being both the best and worst for sustaining wildlife. (Squire *et al.*, 2003 and references therein). The expectation is that future applicants would need to provide information that would allow such wider impacts to be assessed with a similar level of certainty. Given the significance of grassland as a land use system in Western parts of Europe, it is likely that such information would comprise a central element of any dossier on GM forages.

Future Challenges The current regulatory regime has two shortcomings. Firstly only harm is assessed, so it is not possible to argue that adverse impacts in one area are more than offset by advantages in another. Secondly, it only applies to one strand of modern intensive farming. Systems with equal or greater impact (e.g. mutation-bred HT crops) could be introduced without this regulatory process. In the UK, ACRE (the Advisory Committee for Releases into the Environment) has established a sub-group to examine some of these issues in terms of the forthcoming review of the regulatory system (<http://www.defra.gov.uk/environment/acre/meetings/04/min040715.htm>).

Implications for transgenic forages GMHT forage maize has, in principle, been approved for cultivation in the EU. It is, however, an annual with no wild relatives. A recent study on pollen movement in bent grass (Watrud *et al.*, 2004) has indicated how significant gene flow would be when there is a combination of obligate outbreeding and a large pool of compatible wild plants. A previous analysis of ryegrass and *Agrostis* populations using isozyme polymorphisms also established significant long-distance genetic interactions in ryegrass associated with breeding and cultivation that were absent in *Agrostis* (Warren *et al.*, 1998). Risk assessment for GM forages would, therefore, need to concentrate on the impact of the transgene in the natural environment, an interaction that is highly specific to the nature of the transgene. Development of transgenic forages in Europe is likely to be problematic without (a) a change in the regulations to allow consideration of benefit (b) the identification and development of traits that produce such a benefit and (c) the development of more effective genetic and management mechanisms to regulate gene flow.

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