

Genetically Engineered Ornamental Plants: Regulatory Hurdles to Commercialization

Stephen Chandler

The ornamental industry

Ornamental plants are an important sector of the horticultural industry. As the name implies, these are plants grown for their ornamental rather than nutritional value and as such they have a cultural and amenity value integral to everyday life. After several centuries of plant exploration and plant breeding efforts, numerous species of cut-flowers, potted plants, hanging plants, bedding plants, shrubs, and other ornamental plants are available through florists, supermarkets, and nurseries worldwide. The production and distribution of flowers and potted plants is a significant source of revenue to some developing countries in South America, the Middle East, Asia, and Africa. Ornamentals are used in the floristry, gardening, landscaping, and the environmental amenity industries^{1,2}. The total value in the US. for all aspects of lifestyle horticulture is in excess of 175 billion USD³. Combining the production value of ornamentals to the value added to these products, the global value of the ornamentals sector of the horticulture industry is likely to be 250 – 400 billion USD.

Genetic modification of ornamental plants

Genetic engineering techniques offer new opportunities for breeders of ornamental plants. First, where development of new ornamental varieties through hybridization or mutagenesis is difficult or impossible⁴, genetic engineering may provide a solution through gene transfer. Second, genetic engineering can introduce traits that could not be generated by conventional breeding, because the genes of interest do not exist in the natural gene pool^{1,5,6,7}. Third, genes that improve pest and disease resistance in food crops can also be used in ornamentals.

Despite their value, few varieties of GE ornamental plants have been field tested, and the only GE ornamental products that have thus far been released for marketing are color-modified varieties of carnation and rose^{1,8}. Flower color is one of the most important characteristics of ornamentals, and the color range is often limited by the genetics of the plant species^{6,9,10}. Major traits also amenable to manipulation by genetic modification techniques include fragrance, abiotic stress resistance, disease resistance, pest resistance, manipulation of the form and architecture of plants and/or flowers, modification of flowering time, and post harvest

longevity. Pest resistance is particularly important, as prevention of insect damage is one of the biggest costs incurred by growers^{2,7}.

Market acceptance; commercialization hurdles

Genetically engineered flowers have been well accepted in the marketplace for over a decade⁸. A survey of gardeners in Tennessee indicated a majority were likely or very likely to buy genetically engineered ornamentals¹¹.

Given the ability to apply genetic engineering techniques to ornamentals and the positive acceptance in the marketplace, it is perhaps surprising that so few GE ornamental products exist. The reason is due to barriers to commercialization that apply to GE varieties, but not to conventionally-bred ornamental varieties^{1,12}. For ornamentals, which have a much smaller market value than food crops and are normally internationally traded, the cost and difficulty of meeting regulatory requirements is the biggest barrier to commercialization. These costs, which primarily relate to the costs associated with analysis and risk assessment, are not borne in developing non-GE varieties. Promising new non-GE ornamental varieties can be quickly field tested around the world to evaluate commercial potential, but genetically engineered plants must receive prior regulatory approval^{1,13}. The approval process can take many months or even several years. Because the regulation of ornamental plants at both the national and international levels falls under the same legislation that is applied to major food crops, the regulatory scrutiny applied to ornamentals is generally equivalent to crops, with the exception of food safety studies.

Genetically modified carnation with improved vase life has been developed, but not commercialized, because of the cost of regulation¹⁴. Color-modified varieties of the potted plant *Torenia* have also been developed but not commercialised, even though the plant is male and female sterile and has no capacity for gene flow⁹. Again, the cost of obtaining regulatory approval was the major factor preventing commercialization.

The cost of regulation

Significant costs associated with regulatory approval are borne before a product can be tested in the marketplace¹², which increases the financial risk associated with

development of GE ornamental products. The costs incurred seeking regulatory approval for a transgenic event of a major crop plant are estimated to be millions of dollars^{5,15,16}. Though the cost is lower for an ornamental, as no food safety tests are required, there is still a significant cost, potentially amounting to hundreds of thousands of dollars. Higher costs are required to provide a detailed molecular characterization (full sequence of every insert and its flanking region), characterization requirements vary depending on the territory in which the approval is sought. European legislation requires, for example, a full molecular characterization, as well as the same level of molecular analysis for an ornamental as is required for a major food crop, including a verified PCR-based identification test unique for each event, for which a fee of 30,000 EURO per event must be paid prior to validation. The cost of securing regulatory approval also includes the provision of information at later stages of product development as well as earlier research phases. For example, it may be necessary to select for, or develop strategies for, identification of simple (one insert) integration events.

Options to reduce the cost of regulation

There are several options for reducing the cost of regulatory approval for ornamentals.

1. As an alternative to PCR-based unique identification, varieties could be protected by Plant Breeders Rights¹. The morphological descriptors usually used could be supplemented by Southern blots (allowed under the US plant patent system), accompanied by detailed secondary product and/or pigment analysis profiles.
2. Legislation could be modified to allow approval based on phenotype^{12,15} and species, or transformation vector and species, rather than require a separate regulatory assessment of every transgenic event. Compatibility with the Biosafety Clearing House system requirements could still be achieved by allocating unique identifier numbers to each transgenic event. As an example, the color-modified transgenic carnation varieties currently in the marketplace all have the same selectable marker gene and the same altered phenotype (production of delphinidin-related anthocyanins)⁷. It is a costly exercise, for both applicants and regulators, to prepare and review a complete dossier every

time a new transgenic carnation event with qualitatively the same phenotype is produced.

3. The amount of molecular characterization required for non-food genetically engineered varieties could be simplified, reducing the cost of analysis. If a non-food transgenic plant has a low inherent risk of allergenicity, based on the history of the parental organism, then a dossier could comprise a transformation vector map, Southern analysis, northern (RNA) analysis, and proof of absence of extra border integration.
4. In terms of environmental risk assessment legislation, more emphasis could be placed on the lower capacity for gene flow exhibited by plants that are vegetatively propagated or that are completely sterile, such as the *Torenia* mentioned earlier in this article⁹.
5. Legislation could emphasize greater consideration of a history of safe use. For example, some of the color-modified transgenic carnation varieties have been commercially available for more than 12 years and have a proven history of safe use. This history of safe use could be a valid justification for reducing the amount of molecular characterization required, for example.

International harmonization

Another option to reduce cost would be the international harmonization of risk assessment processes^{17,18}. If at least part of the regulatory decisions made by an initial evaluation authority, using internationally standardized protocols, could be adopted by other countries without the need for further assessment, this would be of great help to ornamental breeders who work with products that have a significant international penetration and are often traded internationally.

Prospects and implications for Agbiotechnology

To any one working on the regulation of GE ornamental plants, one of the most striking observations about the global regulatory environment is the different approaches taken by different authorities. In the context of regulatory cost as a barrier to commercialization, this disparity in approach has a direct relationship to the cost of obtaining approval. The cost can range from a few thousand to several hundred thousand dollars per event. The latter case applies to those authorities that require

a full molecular characterization for each event. This includes the EU, which is significant for the ornamental agbiotechnology industry because the EU is the world's largest market for ornamental products and also the home of many long-established ornamental breeders.

Whilst it may make scientific and/or economic sense to reduce the regulatory requirements for some ornamentals by introducing "fast track" mechanisms (for example for GEOs that have a long history of safe use or a low capacity for gene flow), this is not likely to be achieved at the political level, at least not in the near future. The broad experience around the world over the last ten years or so has been that legislative efforts have generally resulted in an *increase* in the requirement for information to support applications for regulatory approval. Given ongoing active opposition to GE plants in some places, there is likely to be little political incentive to reduce regulatory requirements, or to make exceptions

for certain classes of GEO. Also, in some countries the development of legislation has taken many years, and laws have only recently been enacted and committees only recently established. It is unreasonable to expect that these countries will move to new legislation in the near future.

Under the current regulatory environment, the introduction of new genetically engineered ornamentals into the marketplace is likely to continue to be slow and to be largely confined to the North American market. The few ornamentals that will be introduced will probably be important cut flower varieties, as these can be shipped internationally, and so the regulatory assessments of the importing countries do not need to consider production-related issues. The prospects of commercialization for plants destined for sale to the home gardener are currently quite low.

References

1. Dobres MS. (2011) Prospects for commercialisation of transgenic ornamentals. In: *Transgenic horticultural crops; challenges and opportunities* (Mou B, and Scorza R, eds.), pp 305 - 316. Boca Raton, Florida: CRC press.
2. Chandler S and Sanchez C. (2012) Genetic modification; the development of transgenic ornamental plant varieties. *Plant Biotechnology Journal* **10**, 891 – 903.
3. Hall CR and Hodges AW. (2011) Economic, environmental and well-being benefits of lifestyle horticulture. *Chronica Hort.* **51**, 5 – 8.
4. Da Silva JAT, Chin DP, Van PT, Mii M. (2011) Transgenic orchids. *Sci. Hort.* **130**, 673–680.
5. Dobres MS. (2008) Barriers to genetically engineered ornamentals: an industry perspective. In: *Floriculture, ornamental and plant biotechnology; advances and topical issues, vol. 5* (da Silva J.A.T., ed), pp.1 -14. Isleworth: Global Science Books.
6. Debener T and Winkelmann T. (2010) Ornamentals. In: *Genetic Modification of Plants, Biotechnology in Agriculture and Forestry 64*; (Kempken, F. and Jung, C., eds.), pp. 369 – 391. Heidelberg: Springer-Verlag.
7. Chandler S and Brugliera F. (2011) Biotechnology in floriculture. *Biotech Letts.* **33**, 207 – 214.
8. Tanaka Y, Brugliera F. (2013) Flower colour and cytochromes P450. *Phil. Trans. R. Soc. B* **368**, 201220432 <http://dx.doi.org/10.1098/rstb.2012.0432>.
9. Tanaka Y et al. (2010) Flower color modification by engineering of the flavonoid biosynthetic pathway: practical perspectives. *Biosci. Biotechnol. Biochem.* **74**, 1760 – 1769.
10. Nishihara M and Nakatsuka T. (2010) Genetic engineering of novel flower colors in floricultural plants: recent advances via transgenic approaches. *Methods Mol. Biol.* **589**, 325 – 347.
11. Klingeman WE and Babbit B. (2006) Master gardener perception of genetically modified ornamental plants provides strategies for promoting research products through outreach and marketing. *Hort. Sci.* **41**, 1263 – 1268.
12. Sexton S and Zilberman D. (2011) The economic and marketing challenges of horticultural biotechnology In: *Transgenic horticultural crops; challenges and opportunities* (Mou, B. and Scorza, R., eds.), pp 175 - 192. Boca Raton, Florida: CRC press.
13. Underwood BA and Clarke DG. (2011) Transgenic ornamental crops In: *Transgenic horticultural crops; challenges and opportunities* (Mou, B. and Scorza, R., eds.), pp 55 - 82. Boca Raton, Florida: CRC press.
14. Chandler S. (2007) Practical lessons in the commercialisation of genetically modified plants – long vase life carnation. *Acta Hort.* **764**, 71 – 82.
15. Alston JM, Bradford KJ, Kalaitzandonakes N. (2006) The economics of horticultural biotechnology. *J. Crop Improvement*, **18**, 413 – 431.
16. Bayer JC, Norton GW, Falck-Zepeda JB. (2010) Cost of Compliance with Biotechnology Regulation in the Philippines: Implications for Developing Countries. *AgBioForum*, **13**, 53-62.
17. Ramessar K et al. (2009) Calling the tunes on transgenic crops: the case for regulatory harmony. *Mol. Breed.* **23**, 99- 112.
18. Durham T, Douchet J, Snyder LU. (2011) Risk of regulation or regulation of risk? A de minimus framework for genetically modified crops. *AgBioForum*, **14**, 61-70.

Stephen Chandler
 Adjunct Professor
 School of Applied Sciences, RMIT University
 PO Box 71, Bundoora VIC 3083. Australia
 schandler230@gmail.com