BIOSAFETY ASSESSMENT AND BENEFITS FOR CO-EXISTENCE OF BIOLOGICAL CONTAINED PLANTS – REGULATORY ASSESSMENT IN THE EU-PROJECT "TRANSCONTAINER". Christiane Koziolek and Detlef Bartsch, Professor, Federal Office of Food Safety and Consumer Protection, Mauerstrasse 39-42, D-Berlin 10117.

The EU-project TransContainer[1] deals with the evaluation of environmental impact and benefits for coexistence between GM- and non-GM plants. Different containment strategies are applied to a broad spectrum of crops (*e.g.* oilseed rape, sugar beet, tomato) as well as to perennial plants like trees and grasses. The containment methods focus on three strategies: Chloroplast Transformation, Controllable Flowering and Controllable Fertility. Key issues are (a) safety assessment focussing on three points: molecular characteristics, ecology of the GM species and consequences of a potential break-down of the containment system. (b) Benefit assessment of the containment system for the co-existence of GM and non-GM plants. The environmental impact assessment is performed based on the criteria provided by the EFSA Guidance document (2006)[2] for the placing on the market of GM plants in the EU. Additionally to impact assessment, an economic evaluation is performed. The development of contained GM crop plants is still in an early stage and thus our evaluation is focussed on the safety assessment of the general methodical characteristics.

Benefits of Chloroplast Transformed plants: Chloroplast transformation is a promising containment system for plant species with strict maternal plastid inheritance by avoiding the out-crossing of recombinant genes via the pollen. The targeted insertion of a GM sequence in the chloroplast genome by homologous recombination has three advantages: (1) insertional inactivation of unknown functional genes is avoided, (2) endogenic *in-situ* promoters can be used, and (3) even though plastids harbour relatively small replicons, large insertions are tolerated. However, it has to be verified that the transgene is not inserted unintentionally in the nuclear genome since the transformation (*e.g.* particle bombardment technique) could be unspecific.

Benefits of plants with Controlled Flowering: The suppression of flowering is useful for plants that are cultivated for their vegetative parts, *e.g.* sugar beet, grasses or trees. For bi-annual sugar beet, the inhibition of undesired bolting and flowering will either prevent out-crossing and introgression into endogenous beet populations as well as facilitate the cultivation of beets for the farmer. In grasses, flower suppression will improve the fodder quality as the shoots have higher lignin content thus hampering the digestibility of the feed. In trees that are intended to be cultivated in plantations for biomass production, the suppression of flower development would offer certain advantages: GM trees with *e.g.* changed wood properties would neither develop pollen nor seeds containing the inserted DNA, avoiding any unintended hybridisation or spread of the GM seeds by wind. In contrast to trees that can be propagated vegetative, grasses as well as sugar beet need to flower for breeding purposes. Therefore, a molecular switch will be introduced, which will initiate flowering upon an external chemical stimulus. In case of flower induction for breeding, other (physical) measures are requested to avoid unintended out-crossing and spread of hybrids.

Benefits for Co-existence: Regarding the legislation on GM plants in the EU, the minimisation of GM escape via pollen into adjacent non-GM fields or wild relatives is an important point in the improvement of co-existence measures. In chloroplast transformed plants, the spread of inserted DNA is limited only at the pollen level, whereas the (transgene) seeds produced by the mother plant could still be lost or spilled unintended during harvest and transport. Upon complete flower suppression, neither pollen nor seeds will be released, thus gaining a very high level of restriction. The containment measures will allow (i) minimising the isolation distances between GM and non-GM fields, (ii) protecting the GM cultivating farmers for liability claims from neighbours, (iii) reduce conflicts with bee keepers, and (iv) avoid unintended mixtures with food products.

[1] See: http://www.transcontainer.org/UK/
[2] See: EFSA Guidance document of the scientific panel of genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed (2006)