

Development of a sampling regime for research with environmental relevance based on variability of transgene expression in plant

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Introduction

Transgenic plants often produce proteins that are unknown in conventional crops. Therefore it requires a fundamental analysis before approval of a new genetically-modified plant is given. Since the EFSA-guidelines for risk assessment on transgenic plants provide only recommendations but no detailed instructions, we want to develop a valid test scheme that defines sample size and sampling organ to enable a statistically valid and efficient analysis of transgene expression and its variability. The scheme will be developed on model organism potato and will be based on data obtained for the variability in expression

- i. of different recombinant proteins in one variety;
- ii. of different integration sites of one transgene in one variety;
- iii. of the same recombinant protein between different varieties and between isogenic clones in a variety.

The optimization of experimental procedures shall enable the development of cost and time efficient and valid sampling systems that will be used as a part of the Decision Support System (DSS) that is developed by BioOK.



Experiment

The variation of transgene expression in the field was analyzed using the recombinant proteins VP60, NPTII and Cyanophycin-synthetase. Data of transgene expression - generated in the first funding phase BioOK I - were statistically evaluated by BioMath GmbH. Variability was determined and sample size was defined. On this basis in 2009 tubers from 18 plants and leaves from 24 plants per event were used.

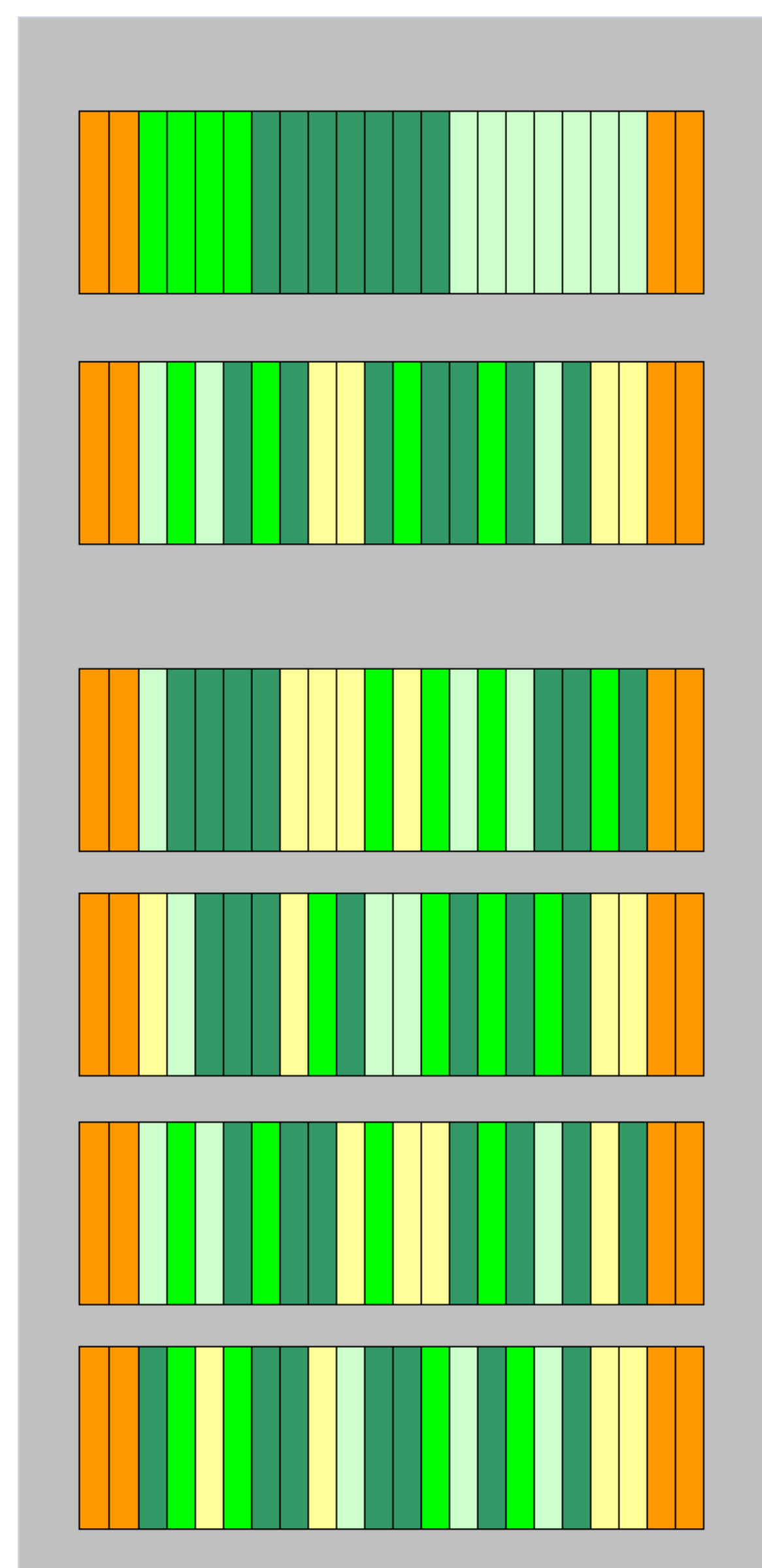


Figure 1: field trial 2009 randomly arranged plots; 13 transgenic events expressing three different recombinant proteins; four near isogenic clones; repeated six times.

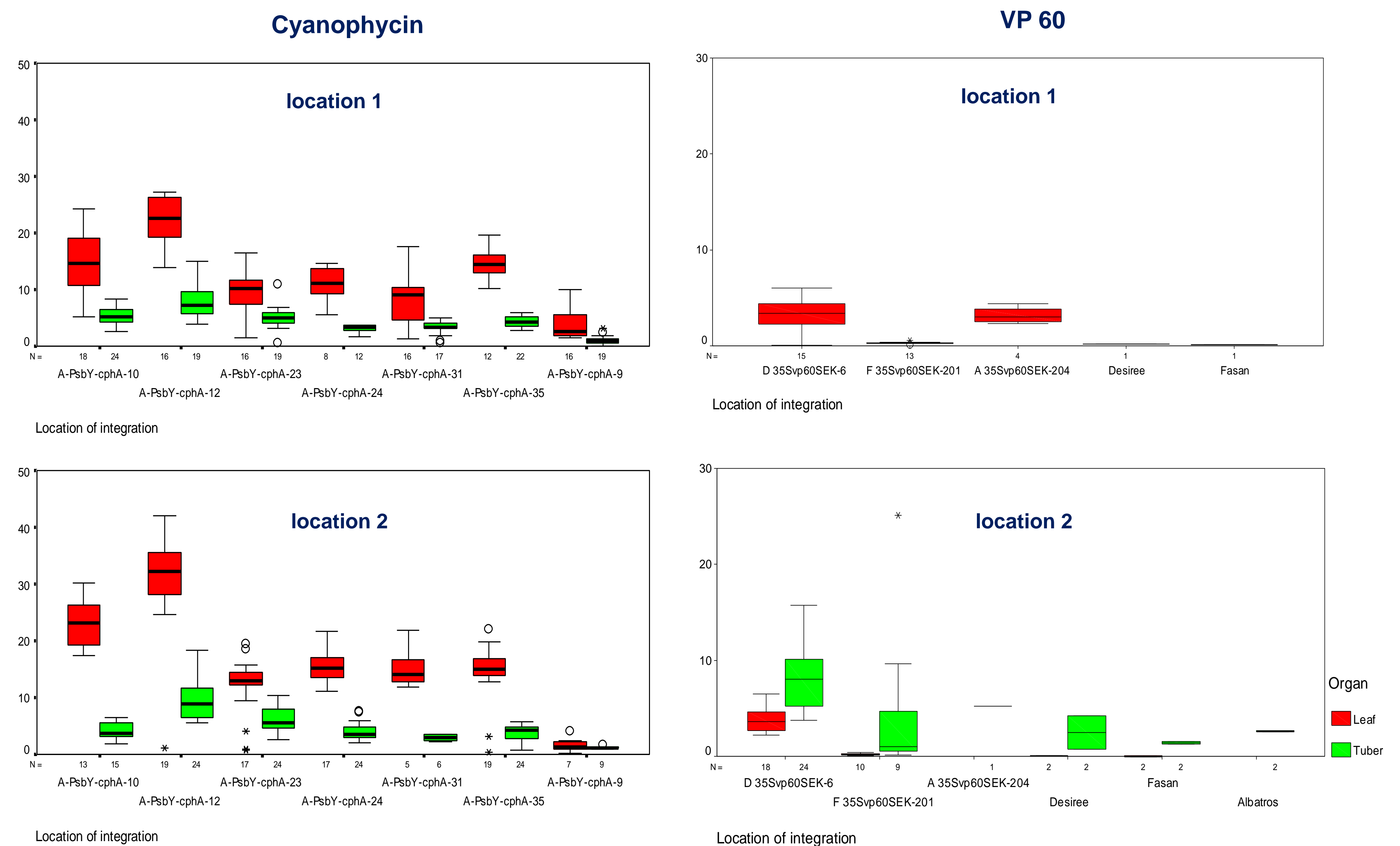


Figure 2: exemplary results of determination of Cyanophycin and the VP60 content. Variation between clones is shown depending on the integration site, the organ analyzed (leaf, tuber) and the field location

Summary

Statistical interpretation of the content of transgene encoded proteins show differences between field location, differences between the plant organ and differences between similar events (integration sites). Hence an individual optimal sample size for the detection of the complete expression range is required for each event. Therefore an universally valid sample size means the maximum of all deduced sample sizes.