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Next-generation sequencing as a tool for the molecular characterisation and risk assessment of Genetically Modified Plants: added value or not?

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23	Abstract
24	Background
25	Legislations and international organizations provide a framework to ensure proper risk assessment of
26	Genetically Modified Organisms (GMO). With regard to the deliberate release of GMO as food or feed,
27	applications for Genetically Modified Plants (GMP) typically contain data for the molecular characterisation at
28	the nucleic acid level based on Southern blot and polymerase chain reaction analysis in combination with Sanger
29	sequencing. Along with the diverse range of applications of next-generation sequencing (NGS) in genomic
30	research, some recent research projects and product developers explored the use of NGS as an alternative tool for
31	meeting the data requirements for the molecular characterisation of GMPs in view of their risk assessment.
32	Scope and Approach
33	By means of a literature survey and information collected through the organisation of an international workshop,
34	we investigated whether NGS can replace and/or complement the currently used techniques for molecular
35	characterisation of GMP taking into account the possibilities and current bottlenecks of NGS technologies and
36	recent developments in molecular breeding.
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37	Key Findings and Conclusions
38	We conclude that although NGS might present clear advantages for product developers, NGS currently does not
39	always offer a significant added value with respect to the risk assessment of GMPs. However, the approaches
40	used so far may soon be further challenged by the fast evolution in NGS technologies and also by the recent
41	developments in molecular breeding of plants. We postulate that setting up a common workflow for the
42	generation of relevant and interpretable data by NGS would facilitate a scientifically sound assessment of

43 GMPs.

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