

Preface

Testing of genetically modified organisms (GMOs) presents significant challenges to the laboratories assigned to this specific task. It requires, among other skills, a profound understanding of molecular biology, the capacity to set up and to use accurate procedures and methods of analyses, including quality management systems, and a permanent adaptation to and knowledge of new GMOs entering the global market.

This book reflects the practical experience and knowledge gained over many years of various activities at the National Institute of Biology (NIB), Slovenia, which is a research organization and National Reference Laboratory (NRL) as well as a laboratory performing routine analyses of food, feed, and seeds. It operates in tight collaboration with the European Network of GMO Laboratories (ENGL) and the Institute for Health and Consumer Protection (IHCP) of the European Commission (EC) Joint Research Centre (JRC). This book is written in cooperation with the IHCP which has extensive knowledge and experience regarding GMO detection and which hosts the European Union Reference Laboratory for GM Food and Feed (EU-RL GMFF) and chairs the ENGL. In addition, high-quality guidance documents produced by various ENGL working groups were of valuable support in writing this book.

This book is intended as an aid to the authorities and testing laboratories, giving essential information on GMO legislation and testing and in addition, profound and precise practical information about the implementation of real-time PCR for both qualitative and quantitative analysis.

PCR-based methods are the methods of choice in the European Union for GMO testing and are becoming recognized as the standards for reference methods. Legal thresholds were set for labeling GMO presence in food and feed in different countries, stimulating the development of approaches for precise quantification of DNA.

Validation and verification of the laboratory methods are two of the prerequisites for quality-assured GMO testing. The parameters of the methods that need to be evaluated, their acceptance criteria, and performance requirements are described in this book.

Measurement uncertainty can significantly influence the decision-making process; therefore it is necessary to set harmonized approaches for measurement uncertainty estimation in order to avoid international disputes caused by differences in the interpretation of results.

A glance at the pipeline of GMOs currently in development suggests that many more and diverse organisms will need to be detected in the future. Moreover, new technologies are being introduced for the further modification of organisms. This diversity in terms of new species, new traits, and new types of modified organisms presents real challenges for future detection. On the other hand, new detection methodologies and techniques are in development, offering high throughput, cost-efficient, reliable, and accurate analysis. The combination of laboratory solutions with bioinformatics tools is expected to be a successful key and approach to meeting new challenges.

There is always room for improvement in the domain of GMO analysis and each of the topics described in the book is constantly evolving. In each section of the book, references to the most informative, comprehensive, and recent literature or websites are given to offer the reader additional information.

The methodological approaches described in the present document are also relevant for other areas where detection and identification rely on nucleic acid-based methods. Additionally, this book can be used by lecturers looking for information about nucleic acid detection and quantification. Metrological topics presented, such as validation, verification of methods, and measurement uncertainty, as well as solutions to guarantee quality assurance, can be of additional importance for the experts in laboratories dealing regularly with implementation of new methods and the setting of laboratory conditions to obtain accurate test results.

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