



# Comprehensive matrices for regulatory approvals and genetic characterization of genetically modified organisms



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## ABSTRACT

The production of new types of genetically modified organisms (GMOs) and the use of products containing or derived from these materials are expanding globally. This poses a challenge in providing cost-effective comprehensive analyses. In this line, the state of art testing approaches rely on a matrix representing the GM events with their corresponding GM markers - DNA elements used in plants' transformation. Accordingly, this study aimed first at constructing an updated and comprehensive matrix of genetic characterization of GM events based on an extensive review of the relevant databases. Inclusive lists of 356 GM markers and 508 events in 29 plant species were compiled and organized into a matrix. The frequency of occurrence of these elements was then determined. Moreover, for the first time, a matrix representing the regulatory status of every compiled GM event was established. Remarkably, numerous inconsistencies were detected among the databases at the levels of nomenclature, events' registry, molecular characterization and regulatory approvals. Both matrices represent a useful tool for comprehensive and cost-effective analyses. The genetic matrix permits designing the most straightforward testing strategy that provides the maximum information about GMOs in a sample in the minimum number of experimental steps. Moreover, the novel regulatory matrix, allows further decreasing the number of required event-specific identification tests by giving higher probabilities to those authorized in the samples' country of origin. Finally, the genetics and regulatory matrices represent the building-block for establishing an inclusive automated database for GMOs which is instrumental for testing laboratories worldwide.

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## 1. Introduction

Genetically Modified Organisms (GMOs) are those whose genetic material has been altered in order to possess novel traits. Genetic modifications are carried out by the insertion of genetic construct(s), which when integrated into the plant's genome constitute(s) a GM event (DG Health and Food Safety, 2017; Gabrielle & James, 1999; Kate, Lina, David, Nicky, & Kerry, 2003; WHO, 2017). GMOs containing more than one GM event combined via conventional crossing of previously existing GMOs are called stacked GM events (Alexander & Emilio, 2009). The production of GMOs is in continuous progression since the mid-nineties. Statistics have shown more than a 100 fold increase from 1996 till 2013, where the global acreage exceeded 175 million hectares (Clive, 2014). In order

to protect the consumer's rights and ensure food and environmental safety, 63 countries around the world have laid down their country-specific regulatory policies to control GMOs authorizations and labeling (Clive, 2014).

The implementation of GMOs regulations requires the availability of analytical methods to detect the presence of GMOs and further identify and quantify the potential GM event(s) in a positively screened sample. The routinely applied testing methods are based on DNA amplification by the polymerase chain reaction (PCR) method (Alexandra et al., 2015, pp. 119–131; Kate et al., 2003; Wentao & Ying, 2015, pp. 343–351).

However, owing to the huge expansion in GMOs production along with a significant increase in the number and genetic diversification of the produced GM events, affordable testing strategies in terms of time and cost have become a requirement. In this context, the testing approaches that are widely adopted nowadays rely on a GMOs matrix, a table representing the list of GM events with their corresponding transgenic elements (Holst-Jensen et al.,

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2012; Querci, Van den Bulcke, Žel, Van den Eede, & Broll, 2010). The number of GM events and targets included in the matrix are flexible, and can be increased or decreased according to the available information and specific needs (Holst-Jensen et al., 2012). The first GMOs screening matrix was established in 2010 and it included 81 GM events and five PCR targets (Waiblinger, Lutz, Mankertz, Engelbert, & Pietsch, 2010). Further efforts were made to establish larger databases for GMOs screening such as the GMO finder and GMO seek which include 324 and 328 GM events, respectively (Gerdes, Busch, & Pecoraro, 2012; Morisset et al., 2014). Such genetic matrices are crucial to significantly minimize the number of required analytical steps for GMOs analysis.

Previously published matrices were based on a genetic representation of the collected GM events with their corresponding genetic elements. Therefore, we intended in the current paper to extensively review the main related GMOs databases in order to provide an updated genetic matrix. Moreover, as the available matrices are exclusive to genetic characterization of GMOs, we established for the first time, an additional comprehensive matrix for the regulatory approvals of all GM events.

The reviewed databases are the Gene and Living Modified Organisms (LMO) registries of the Biosafety Clearing House (BCH Gene Registry, 2016; BCH LMO Registry, 2016), the GM Crop Database of the Center for Environmental Risk Assessment (CERA GM Crop Database, 2016) and the GM Approval Database of the International Services for the Acquisition of Agri-Biotech Applications (ISAAA GM Approval Database, 2016). These databases were selected based on their extensive use in the field of GMOs analyses.

The novel matrix representing the regulatory status of each GM event triggers additional decrease in the number of required GMOs tests, whereby analytical priorities will be given to the GM events that are authorized in the sample's country of origin. The matrix is therefore of special importance in countries that have not developed yet their GMOs regulations. This is the case of most of the Middle East and North Africa (MENA) countries where the absence of regulations has allowed introducing GMOs into the MENA markets (Abdel Mawgood, Gassem, Alsadon, Alghamdi, & Al Doss, 2010; Al Hmoud, Al Rousan, Hayek, & Ibrahim, 2010; Al Rousan, Al Hmoud, Hayek, & Ibrahim, 2010; Bakr & Ayinde, 2013; El Sanhoty et al., 2002; Herzallah, 2012; Oraby, Hassan, & Abou Mossallam, 2005; Premanandh, Maruthamuthu, Sabbagh, & Al Muhairi, 2012; Sakr, Mallah, Chalak, & Abou-Sleymane, 2014). Yet, GMOs analysis is still requested in those countries by local seeds, food or feed stakeholders who intend to voluntarily label their products with information about GMOs for marketing purposes. It is also requested by some local manufacturers who export their products to countries with implemented GMOs regulations.

Therefore, the two matrices provided in this paper represent an informative, cost and time efficient tool for GMOs analyses. They also serve as a sweeping source of information on GM events genetic characterizations and regulations, and are the basis for establishing comprehensive and automated databases for GMOs.

## 2. Materials and methods

### 2.1. Establishing the genetic matrix

Data about the registered GM plant species were retrieved from the three databases: Living Modified Organisms (LMO) registry of the Biosafety Clearing House (BCH), GM Crop Database of the Center for Environmental Risk Assessment (CERA) and GM Approval Database of the International Services for the Acquisition of Agri-Biotech Applications (ISAAA) (BCH LMO Registry, 2016; CERA GM Crop Database, 2016; ISAAA GM Approval Database, 2016) and then cross-compared in order to establish a

comprehensive list. The recorded GM events in each species were then compiled from the three databases, compared for consistency, and then an inclusive list was established. Further, the genetic elements associated with each GM event were collected and a complete list of DNA sequences of the inserted genetic constructs used in plants' transformation was established. The elements of few events that are not fully genetically characterized in these databases were retrieved from Biosafety Scanner (Biosafety Scanner, 2016). Subsequently, a comprehensive matrix representing all plant species with their respective GM events and DNA elements was established, and the frequency of occurrence of each of these DNA elements in GM events was calculated.

### 2.2. Establishing the regulatory matrix

A second new matrix representing the regulatory approvals of each included GM event was constructed by collecting the information from BCH-LMO Registry (BCH LMO Registry, 2016), CERA-GM Crop Database (CERA GM Crop Database, 2016) and ISAAA-GM Approval Database (ISAAA GM Approval Database, 2016), comparing them for uniformity, and organizing them in an inclusive table. The three databases provide summary of authorizing countries and approved type of use of each GM event. The webpage last update for each authorization retrieved from these databases is included in the matrix to facilitate future updating. Moreover, authorizations from the database "Biostradestatus", an external database provided in the BCH, have been included when they were not reported in the BCH itself.

The compiled data for both matrices of genetic characterizations and regulations were double checked to diminish the rate of error. They were last updated in June 2016.

## 3. Results

### 3.1. Compiling lists of GM events

A list of 507 GM events from 29 plant species (Table S1) was compiled from the main GMOs databases (BCH-LMO registry, CERA-GM Crop Database and ISAAA-GM Approval Database). All these databases list the worldwide authorized GM events/species. Eight of the 29 compiled plant species are not registered in GM Crop Database of CERA (*Phaseolus vulgaris*, *Solanum melongena*, *Eucalyptus* sp., *Petunia hybrid*, *Prunus domestica*, *Populus* sp., *Saccharum* sp. and *Capsicum annuum*), and two plant species are not recorded in the LMO registry of BCH (*Saccharum* sp. and *Capsicum annuum*).

Among the 507 unique GM events, 220, 391 and 425 were found to be registered in the CERA-GM Crop Database, ISAAA-GM Approval Database and BCH-LMO registry, respectively. 210 of the collected GM events are commonly registered in the three databases, 100 events are registered in BCH and ISAAA only, eight GM events are registered in CERA and ISAAA only, a GM event is registered in BCH and CERA only, 114 GM events are recorded in BCH only, 73 GM events are listed in ISAAA only, and one event is registered in CERA only (Fig. 1). The GM events that are authorized in EU or have an application being submitted were also retrieved from GMO Compass (GMO-Compass, 2015) and checked if they are included in the other three databases. All of them were found to be registered, except for the maize event NK604 × T25 which has a submitted application according to GMO Compass and which was not found registered in any of the databases, raising the number of compiled GM events from 507 to 508.

Since all products containing or consisting of GMOs are required to be labeled by the unique identifier assigned to each GM event (EC 65/2004) (OECD, 2006), the unique identifiers of all compiled GM

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