Qualitative risk assessment for adventitious presence of unauthorized genetically modified organisms

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ABSTRACT

The adventitious presence of unauthorized genetically modified organisms is becoming a concern for producers, manufacturers, consumers and other participants in the supply chain of food and feed products. A special part of a decision support system was dedicated to this problem in the Co-Extra project (Co-Extra: GM and non-GM supply chains: their CO-EXistence and TRAceability EU FP6 Integrated project 007158). In this paper, the context of the problem is described and a prototype solution in the form of two decision support models is suggested. The models are presented in detail with a special focus on their comparison from a user's perspective and from the perspective of expressive power. The paper concludes with comments and suggestions for similar decision support tool implementations.

Key Words: *decision support, genetically modified organisms, food supply chain, UGM, DEX*

1 INTRODUCTION

Classical plant breeding techniques like the production of hybrids were supplemented in the last few decades by modern genetic engineering technology that allows various gene modifications and (re)combinations, including the use of genes from completely unrelated species. When we talk about genetically modified organisms (GMOs), we refer to products of the latter technology.

The use of GMO crops represents a major technological breakthrough in agronomy. It is a technology that enables numerous interesting and valuable uses, but also raises environmental, economical and political concerns (van den Bergh and Holley, 2002). Significant research effort was dedicated to these and other aspects on the use of GMOs.

With increasing numbers of newly developed GMOs, the asynchronicity of availability and authorizations in different jurisdictions is expected to increase (Holst-Jensen, 2009). As the technology is becoming widespread, there will also be an increasing amount of potential sources of new and undocumented GMOs. Detection focus might thus be shifted from the detection of authorized GMOs to the detection of unauthorized GMOs (UGMs), both qualitatively and quantitatively. The problem of UGM detection is not yet a crucial one, but it has a potential to become important in the future. In this paper, two prototype solutions to detection of UGMs are presented.

Some insight into what UGMs are is provided in the next section. The third section continues with an explanation of some detection approaches. Our methods and software solutions are

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presented in section 4, where two distinct approaches are presented in detail. The differences of the two solutions are discussed in section 5 and followed by conclusions in section 6.

2 UNAUTHORISED GMO

A GMO can be considered unauthorized for various reasons. It can be banned, it can be authorized only for specific use (e.g.: for use in food and feed products, but not for environmental introduction), it can be in the process of authorization, it can be no longer authorized, or it can be completely unknown to the competent authorities.

An example of a banned GMO is for instance the StarLink corn which was authorised only for animal feed and not for food, but was detected in some food products nevertheless (Clapp, 2008) and was subsequently banned for all purposes as it could not be established that the maize had equal allergenic properties as the unmodified maize. As the process of authorisation in the EU is slower and more complex than in the USA, there are numerous products that are known, but are often still in the process of authorisation. So far, there were only cases in which these showed up unexpectedly, but no completely unknown and undocumented GMOs were detected.

The presence of UGMs is not allowed in food and feed products on the European market (EC, 2003a; 2003b). As a consequence, detection of UGMs (Demeke et al., 2006; Clapp, 2008; Quirasco et al., 2008) in specific raw materials and/or processed products will lead to withdrawal of the products involved. This can have severe economic consequences for the marketing stakeholders. Therefore, it is valuable for the producers in the production chain to have tools to perform a qualitative risk assessment in dealing with UGM-material. Our first attempt in this direction is presented in section 4.

3 METHODS OF DETECTION

For authorised GMO products, an analytical method for detection and identification must be provided by the producer (the seed company). If such method exists for a specific UGM, then its detection is straightforward. However, usually such methods will not be available for GMOs not yet submitted for market approval and for the completely unknown GMOs we cannot expect them to be available. Without specific methods, there is a possibility to detect an UGM by conducting a series of tests for features of authorised ones and analysing the results for combinations of markers, which do not belong to any of the authorised GMOs (Prins et al., 2008). Obtaining such a result through analytical detection would be a clear indication that the sample under analysis contains a UGM. Although such analytical approach can sometimes result in clear indications, there is no guarantee that an unauthorised product would be detected. Another drawback is the high cost and time consumption of this approach.

In this paper we present another, complementary approach to the problem that is based on the use of documentary traceability data and expert knowledge. The documentary traceability data accompanies the product and describes its geographical origin and path in the production/supply chain. For experienced experts, such data can represent valuable information for assessing the possibility of UGM presence. Expert knowledge can be elicited and represented in decision models, which can be used for providing quick indications for the analysis of a given problem. In this case, software implementation of such a model could ask the user for the documentary traceability data and provide a qualitative answer regarding the possibility that the product at hand contains UGMs. Although we can never get clear results with the use of documentary traceability data, as is the case with the analytical approach, we always obtain an indication, which is given quickly and without additional costs.

4 DECISION SUPPORT SOLUTIONS

In the next two subsections we present two prototype decision support solutions, which are based on expert knowledge modeling and the use documentary traceability data. The objective of the tools is to estimate the risk for food producers of the presence of UGMs in (purchased) raw materials and/or derived products. This estimation is approximate and qualitative in terms of very-high, high, medium, low and very-low.

4.1 Decision tree

Prior to any decision modeling, there is a phase of expert knowledge elicitation, where relevant information about the problem is gathered and decisive factors are identified. In the first stage, this knowledge is represented with sketches, mind-maps, diagrams and alike. In our case, the domain experts provided a formalised and useful diagram already from the start. The diagram that represented the problem of assessment of the risk of the presence of unapproved GMOs was formed as a simple decision tree (simple as without any chance nodes and with qualitative outcomes), depicted in Figure 1.

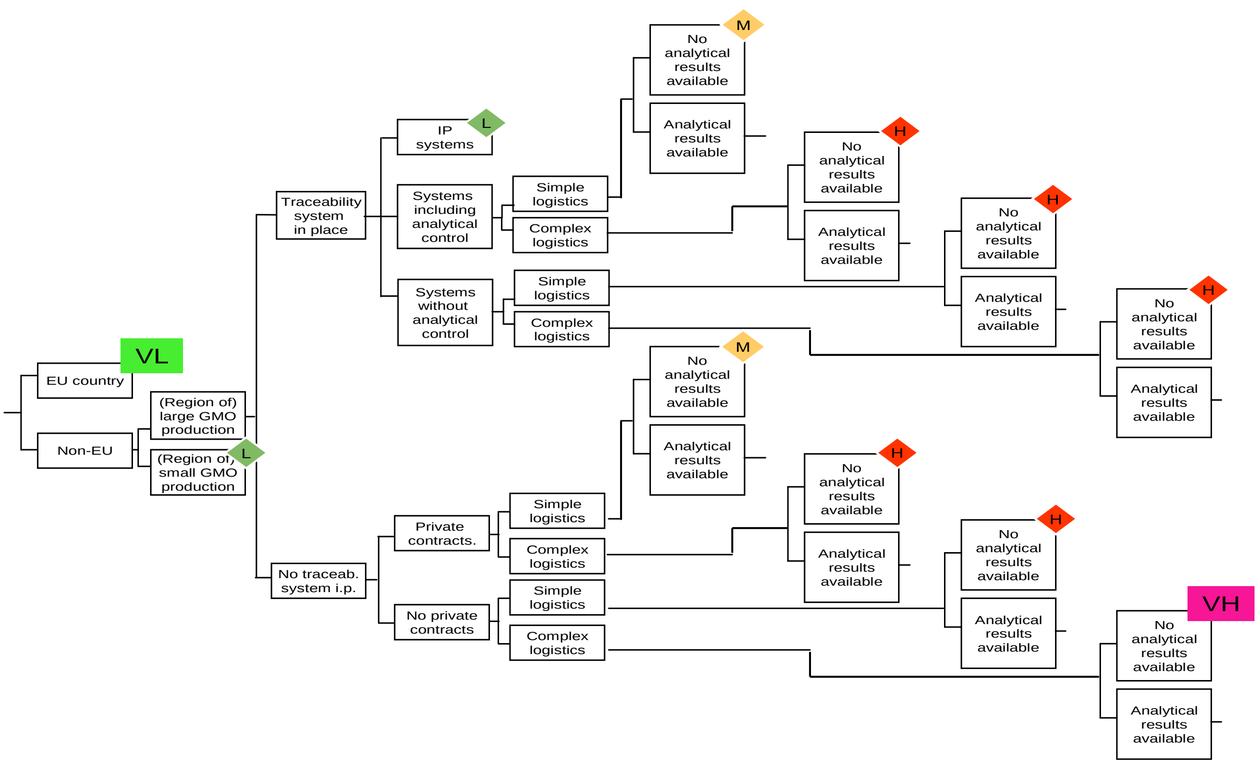

Figure 1: Decision tree diagram for the assessment of the risk of the presence of UGMs.

The decision tree representation was intended only as the initial step towards a more comprehensive hierarchical rule-based model. But as it was very simple and natural representation for the experts and at the same time seemed quite complete, we decided to make an intermediate implementation already of this model. The decision tree from Figure 1 was implemented as web-application with a user interface in form of a wizard (available at http://kt.ijs.si/martin_znidarsic/CoExtra/ugmtree/ugmtree.html).

The use of a simple decision tree representation facilitated a fast initial development of the model, which was found very comprehensible and easy to communicate. However, as the decision trees are gradually extended, they become more and more complex and difficult to maintain. To cope with complexity, the decision tree was converted into an equivalent two-level hierarchical rule-based model, which is presented in the following subsection. This model was extended further by adding new levels and new attributes, in particular at the part addressing logistics and analytical results.

4.2 Multi-Criteria Model

Hierarchical multi-criteria decision models hierarchically decompose the main concept of the problem to sub-concepts and finally to basic concepts or basic attributes, which can be measured and are provided as the data input to the model. In our case, the basic attributes are the characteristics of the production chain that are described in documentary traceability data. Basic attributes are aggregated into higher level attributes with value functions. In the case of DEX methodology, our model of choice, the values of the attributes are qualitative and the value functions are rule-based (Bohanec and Rajkovič, 1990; Žnidaršič, Bohanec and Zupan, 2008). A model of this kind was developed for the problem of UGM detection on the basis of decision tree formulation from section 4.1 and implemented in DEXi decision modeling toolbox (Bohanec, 2008). The rules in the model were specified in more detail and the model itself was extended further. A complete attribute structure of the final model is shown in Figure 2.

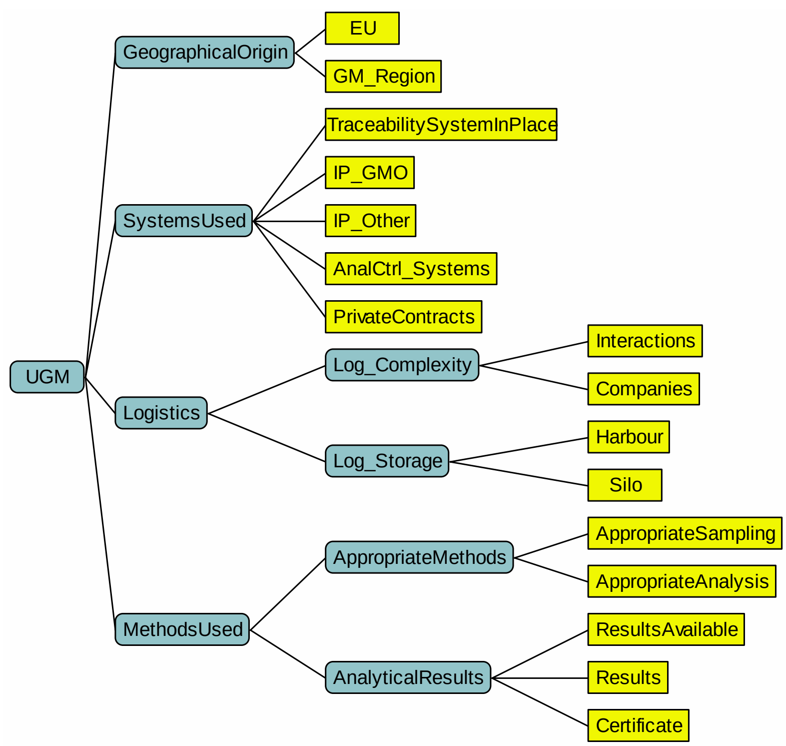

Figure 2: Structure of the hierarchical rule-based model for the risk assessment of UGMs.

The root attribute *UGM* represents the risk of UGM contamination, which can be: [very-high, high, medium, low, very-low]. The risk is determined according to four main subgroups of attributes:

1. *GeographicalOrigin* of the product,
2. *SystemsUsed* in previous stages of the supply chain in order to produce traceability data,
3. *Logistics* that was applied to bring the product to the current point in the supply chain, and
4. *AnalyticalMethods* that might have been applied previously and whose results may (but need not) be available at present.

In the model, all these four attributes use a three-valued qualitative scale [high, med, low], which represents the expected risk level originating from each of these attributes; this risk level is determined by the corresponding submodels.

The *GeographicalOrigin* submodel estimates the risk of UGM contamination based on two criteria: (1) *EU*: Does the product originate in an EU country? (2) *GM_Region*: Does the product originate in a region of large GMO production? In principle, products originating in EU are of low risk. The risk from other countries depends on *GM_Region* and is generally high if it originates in a region of large GMO production.

SystemsUsed is a submodel that addresses risks associated with the traceability systems used in the production/supply chain. First of all, we need to know whether the traceability system is in place or not (*TraceabilitySystemInPlace*). The presence of any regularly used traceability system considerably reduces the risk. The risk is further reduced with the application of *IP* systems (systems including full data recording on subsequent steps in the production chain, collection of samples, and analysis of samples at all stages) and *Analytical Control* systems (those that can not be considered IP systems, but do include analytical control steps). The fourth system-related basic attribute, *PrivateContracts*, applies particularly to situations in which there is no (regulatory) traceability system in place, but segregation may still be warranted if there is retribution or fine for non-compliance.

The *Logistics* submodel addresses the type and complexity of logistics that brought the product to the present point in the supply path. The more complex the logistics, the higher the likelihood of commingling the product with UGMs. Here, we consider two aspects of logistics:

- *Log_Complexity*: The complexity of logistics in terms of the number of *Interactions* (logistic steps at which product is transported and potentially mixed with other products) and the number of *Companies* carrying out the logistics.
- *Log_Storage*: Existence of particularly risky storage places in the path, especially *Harbours* and *Silos*.

The last submodel, *AnalyticalMethod*, addresses the methods carried out in the supply path and results obtained by these methods, if they are available. There are two aspects:

- *AppropriateMethods*: A judgment of methods that have been used to obtain traceability data: are they appropriate or not? Both sampling and analytical methods are considered and assessed by two basic attributes, *AppropriateSampling* and *AppropriateAnalysis*, respectively.
- *AnalyticalResults*: Assessment of risk with respect to analytical data. The data can be available or not (*ResultsAvailable*). The risk is higher when data is not available. If the data is available, we also look at the *Results* and see if they indicate any GMO presence and of which type (approved or unapproved). A non-GMO result from a trusted source lowers the risk, whereas any GMO content increases the risk and potentially requires additional analyses. The fact that no specific methods will be available for many (EU-)unapproved GMOs is taken into account here.

5 COMPARISON

The two decision support solutions are similar by contents, but their methodological and technological differences are substantial. Both are compared here from various aspects. The following tradeoffs were observed:

- *Simplicity of use*: The decision tree representation is simplified regarding the contents, but it is also much simpler to use. The user is asked for data in an iterative way and the process is stopped as soon as there is enough data to come to a conclusion. There is no installation needed in case of the web-application, it runs without emulators on many platforms, and also on PDAs. On the contrary, the models of DEX methodology expect all data input at the start, even data that might turn out to be overshadowed by some important values that are therefore redundant. However, DEXi can handle missing inputs and is more robust in that respect. The hierarchical model is bound to DEXi software, which runs directly only on MS Windows platforms. As DEXi is a powerful software package for development and use of general hierarchical models, the use of the model is not as simple as in the case of the former, specific solution.
- *Scalability*: The possibility to easily expand as the new and more detailed knowledge become available is a very important feature of prototype applications. The model in decision tree form is not good in this respect, as the tree exponentially 'explodes' as is grows larger. Growth is much less of an issue in models of DEX methodology.
- *Representational power and coverage of the problem*: The representational power of the two methodologies is theoretically the same. In practice, the hierarchical rule-based models usually describe problems in much more detail before they would become intractable. As the rules in these models are prepared according to all the combinations of attribute values, the coverage of the problem described with basic attributes is complete in the sense that it covers all, including atypical situations. Our two solutions are therefore very different with respect to representational power. The difference is best described with the number of situations (i.e. combinations of inputs) that the presented models can cover. The decision tree model covers 27 different situations, whereas the DEX model covers 147456 different input combinations. Because DEX methodology models have good coverage of the modelled problem and since DEXi allows for various kinds of their analyses, they are well suited for analyses of decision problems and situations, as well as for knowledge representation and dissemination.

6 CONCLUSIONS

Two solutions to the problem of UGM detection with (primarily) documentary traceability data were presented, using the approach of decision trees and multi-attribute models, respectively. They have different characteristics, which makes them suitable of different uses and makes them complementary. Both of them cover different sides of simplicity/completeness and redundancy/coverage tradeoffs and therefore represent a useful combination of approaches to a single problem.

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