Concepts for general surveillance: VDI proposals
Standardisation and harmonisation in the field of GMO-monitoring

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Abstract:
GMO-monitoring is demanded in the European directive on the deliberate release of genetically modified organisms into the environment (2001/18/EC) as well as in the German Act on Gene Technology.
It is essential for a safe implementation of genetic engineering to accomplish environmental surveillance. It needs to be assured that results are precise and specific and that collected data is comparable. The early and certain detection of environmental effects caused by GMO demands accepted and standardised methods.
The Association of German Engineers (VDI) works on developing a body of regulations of specific methods for a GMO-monitoring. This standardisation-project is funded by the German Federal Agency for Nature Conservation. By applying those methods it can be guaranteed to fulfil legal requirements.
Out of the series VDI 4330 four guidelines covering the exposure of GMOs and molecular analytics have already been published as drafts. Due to the reference to the European legislation and the comparable requirements in the European Union these guidelines were published in German and English. They can be purchased separately or within the VDI-Handbook Biotechnology Part 1: GMO-monitoring. Futher guidelines are on their way and will be published soon. Information on current publications can be received via internet: www.vdi.de/gmo

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1. Introduction

With 128,000 members, the VDI is one of Europe´s largest technical and scientific associations. As recognised representative of the engineers and technology, the VDI generates and bundles a broad knowledge with more than 10,000 experts. These VDI experts establish an essential and trend-setting basis for professional needs, the scientific world and legislation: the VDI guidelines.
VDI guidelines, developed by experts in voluntary responsibility, describe the current state of technology. By this contribution, the VDI promotes innovations and creates security and confidence. Technical regulations do not restrict but support the national and international exchange of goods and services.
VDI guidelines standardise the demands, made on material and immaterial goods, provide comparability and avoid adaptation costs. The acceptance of the German set of rules is of importance for the German economy and is therefore strongly supported by the VDI.

VDI guidelines have a particular legal importance at the national level, for example by their inclusion in acts, ordinances, decrees or regulations. In such cases, the legislator generally refers to the corresponding VDI guideline.
VDI guidelines that relieve the legislator are deregulating because the state passes the right of description of the current state of technology to the VDI. As a consequence the legislator is relieved noticeably and the economy participants have a voice and can strengthen their interests.
Contractual partners also use the VDI guidelines for their contracts under private law. Thereby they assure the necessary legal security of their contractual agreements by considering the current state of technology.

The preparation of standards for environmental protection and for environmental management has made a considerable contribution to today's high level of environmental protection (e.g. in the field of air quality, soil protection and others). This becomes possible due to a strong link between legal and technical rules being effective in this field. High demands are made on the development of the VDI guidelines:

-Participation of the public and lobbies
-Proceeding according to defined rules of procedure
-Obligatory justification of the decisions made
-Transparence of data collection, data evaluation and criteria of the standard approach
-Obligatory review

Before starting a new standardisation project in the VDI, an examination is carried out by the responsible Advisory Board, in which the current need, the compliance with general criteria and the interest of the parties involved is inquired (figure 1). Furthermore, parallel work of others (CEN, ISO, other national regulators) must be excluded. Therefore, newly begun standardisation projects are reported before starting the work. The professionals involved in the respective development of rules are appointed to a corresponding committee after the standardisation contents have been checked by the responsible VDI division. The participating experts bring their own competent view to it and do not participate as e.g. representative of their organisation.
In the following, the committee develops an internal preliminary draft that can be passed as draft after a corresponding, intensive review. This draft is printed and available internationally at the Beuth publishing house (www.beuth.de) and its distribution network. The draft will be subjected to an approval procedure in which everybody can participate. After all objections have been handled and the draft is revised by the issuing committee and after report in the responsible Advisory Board, the final VDI guideline can be passed. The aim of this procedure is to reach a consensus as extensive as possible. At the latest 5 years after its publication, a VDI guideline must be checked for its validity and, if necessary, revised or withdrawn.

The procedure of determining a technical standard - especially the direct participation of the public - guarantees a high level of transparence so that the results of the standardisation are considered as a generally accepted "State of the Art" and can be consulted as decision guidance in the firm establishment and execution of legal regulations. Thus, it is made possible to increase the quality of tenders for measuring programmes and expert's reports considerably, to provide legal certainty for the user and to secure a later comparability of the data.

Figure 1. Simplified flowchart of the approval procedure of a technical standard

2. Standardisation in the field of GMO-monitoring

For a dedicated GMO-monitoring, it is also indispensable to use standardised and controlled procedures (SRU 1996, 2004). Only like this, the monitoring data are evaluated comparably and thus, the planning security for the user of the technology can be provided. The standardisation of methods seems to be the more urgent, the more parties of different institutions are participating in the execution of the data collection.

In Germany, many methodological approaches were developed by research programmes (Zueghart and Breckling, 2003). The implementation of these research results in standards in Germany is presently done by politically independent expert circles in the VDI. This activity is being subsidised by an R&D-project with funds of the German Federal Agency for Nature Conservation and the German Federal Ministry for Environment, Nature Conservation and Nuclear Safety since 2004 and accompanied by the VDI Field of Competence Biotechnology (Berhorn et al., 2005). The corresponding guidelines for a GMO-monitoring are developed in the series VDI 4330.

The VDI guidelines of the series 4330 are directed towards all parties participating in the GMO-monitoring. These methods are suitable both for scientists in the research field and authorities or applicants obliged to carry out monitoring.

At the moment, approximately 160 experts in the Advisory Board GMO-monitoring, 10 expert committees and other assisting groups within the VDI deal with the standardisation of suitable test methods. Hereby, the different aspects of the GMO-monitoring, such as exposition, biomolecular analysis or the registration of direct and indirect effects of GMO, are treated.

First drafts were published in 2005 (table 1). The so-called framework guideline “VDI 4330 part 1: Monitoring the ecological effects of genetically modified organisms — Basic principles and strategies” was the first draft published in may 2005. The framework guideline shall merge the other guidelines, which mainly describe appropriate methods. This guideline explains essential concepts of the European guidelines, acts and regulations. In addition, the possible environmental effects of transgenic crop - on multiple ecosystemic levels - are described. A major topic of this guideline is the description of requirements for a monitoring concept. Aims and goods of protection are listed and checkpoints that have to be considered for monitoring purposes are compiled. These checkpoints are used to adequately describe the state of the goods to be protected. The monitoring requirements are substantiated by describing the criteria for the selection of monitoring areas, analytical methods, for quality assurance and documentation of parameters, methods, survey intervals and survey areas.

Table 1. First drafts of VDI guidelines for a GMO-monitoring

Two further drafts were published in June 2005, both dealing with the collection of pollen. Aim of the guideline VDI 4330 Part 3 “Monitoring the effects of genetically modified organisms (GMO's) — Pollen monitoring — Pollen sampling using pollen mass filters (PMF) and Sigma-2 samplers” is the standardisation of a pollen sampler, the pollen mass filter (PMF). Pollen dispersion contributes significantly to the distribution of genetically modified plants. The PMF is used complementary to the sedimentation sampler Sigma-2 according to VDI 2119 Part 4. This guideline deals with specific supplements required for GMO-monitoring. Sigma-2 samplers determine the pollen count deposition rate and allow for direct light-microscopy analyses with regard to species and number of pollen grains on the surface of deposition. The pollen mass filter is designed to provide a 50 to 100 times higher collection efficiency than the Sigma-2 sampler. The high amounts of collected pollen enable DNA analyses (PCR) of samples for possible GMO contamination. Criteria for sampling, quantitative and qualitative evaluation are given in the guideline. Specific parameters, comments on validating this method, its sensitivity, and detection limits as well as its reproducibility are also described.

The other guideline on pollen monitoring is the VDI 4330 Part 4 “Biological sampling of pollen — Bee hives as biological pollen samplers”. It explains a standardised procedure for a biological sampling method. Bee colonies can be regarded as area-specific collectors. Bees actively graze through a specific area. Their collecting activity and the usage of available area are determined by nectar and pollen supply. Honey or bee-bread can be used as starting material for analysis. Since a continuous input of honey and therefore its availability is ensured, its use is advantageous when compared with bee-bread. Moreover, honey is a matrix that is currently easier to handle than bee-bread with regard to light microscopy and molecular-biology analyses. Criteria for sampling, quantitative and qualitative evaluation are given in the guideline. Specific parameters and comments on validating the method are also included.

The fourth guideline published as a draft in 2005 is the VDI 4330 Part 7 “Monitoring the effects of genetically modified organisms (GMO's) — Qualitative methods for the detection of genetically engineered nucleic acids in the environment”. The aim of this guideline is the standardisation of a qualitative detection method for GMO's in the environment that is based on the polymerase chain reaction (PCR). Detection of genetically engineered nucleic acids is of major importance when monitoring GMO’s. The procedure described in this guideline is suitable for analyzing various matrices used as starting material such as plants, soils, or compost. Detailed information regarding specific procedures is given in various appendices. Using a qualitative PCR approach, specific target sequences are detected in the analyzed sample. Analysis consists of amplification under defined conditions, detection of specific target sequences, and confirmation of

specificity of the amplified fragment. Instructions for nucleic-acid extraction from various matrices are not contained in this guideline. Information on evaluation of PCR data and quality assurance is included.

All drafts are currently under discussion.

Several other VDI guidelines are presently worked on. These are guidelines for molecular genetic analytics, methods for the detection of potential effects on soils or soil organisms and other methodological approaches such as the detection of insect resistance (Bt corn). These include e.g. the standardised recording of vegetation surveys for estimating the diversity of plant species or the standardised sampling of butterfly species (table 2).

Table 2. Further standardisation projects

3. National and European standardisation – future prospects

The realisation of the European Single Market results in the fact that more and more national legal rules originate in guidelines, ordinances and decisions of the European Union (EU). Especially in the section of environmental protection this becomes apparent. Meanwhile 70 % up to 80 % of the environmental legislation is not anymore determined by the national member bodies, but takes place in Brussels. For a uniform execution of the EU Directives European Standards are important components. The European standardisation should be built up on existing national standards. With the preparation of corresponding Technical guidelines, which also can be ordered by the European legislator, the European Organisation for Standardisation (CEN) becomes major important by relieving the legislator and by making the knowledge of the experts participating in standardisation usable.

CEN – the New Approach
The majority of the current National Members founded the European Committee for Standardisation, CEN, in 1961. It was first based in Paris. In 1975, CEN moved to Brussels, acquired formal statutes and was registered as a non profit-making, international, scientific and technical institution. The CEN members are the standardisation bodies of all European and EFTA countries.
In its resolution of 7 May 1985 which refers to a "New Approach" in the field of technical harmonisation and standardisation, the European Council decided a division of work between the European legislator and private standardisation. The division of work is based on the principle that the European legislator limits the harmonisation of official regulations to basic necessities and commissions the private standardisation bodies, such as CEN, with the preparation of European Standards for the regulation of technical matters, taking into account the current State of the Art of science and technology (figure 2). By being linked to European legislation, European Standards become an important component for policy and for the coherent application of EU Directives. For the European standardisation organisations this practised "division of work" means without any doubt an endorsement of their work and contributes significantly to deregulation.

Figure 2. European Standardisation. The “New Approach”

4. Conclusions

Also in the field of GMO-monitoring, the central requirements are made in Brussels with the European directive on the deliberate release of genetically modified organisms into the environment 2001/18/EG and the accompanying regulations. With the standardisation of test methods, on the development of which different institutions and organisations have been working for years, a first step was taken now in the VDI to ensure an - at least - Germany-wide comparability of future surveys and to provide legal certainty for the user. Because of the standardisation, it is made sure that the essential requirements - among others also those of the Directive for transparence in the procedure - are fulfilled (Berhorn et al., 2005).

The aim beyond it, however, should be to facilitate a comparability of surveys Europe-wide. Therefore, the VDI Field of Competence Biotechnology strives intensively towards a Europe-wide harmonisation of the procedures (Peichl und Finck, 2003). In order to get in touch with the representatives of the EU and the European member states as soon as possible, the first results of standardisation were presented in Brussels in April 2005 to representatives of the EU Commission, the European Food Safety Authority (EFSA), the Joint Research Center (JRC) and the member states. Also in this conference, it was noticed that it must be a common aim to use the experiences obtained in the member states in the field of GMO-monitoring for a common development of harmonised methods. A Europe-wide harmonisation of the methods is indispensible.

5. References

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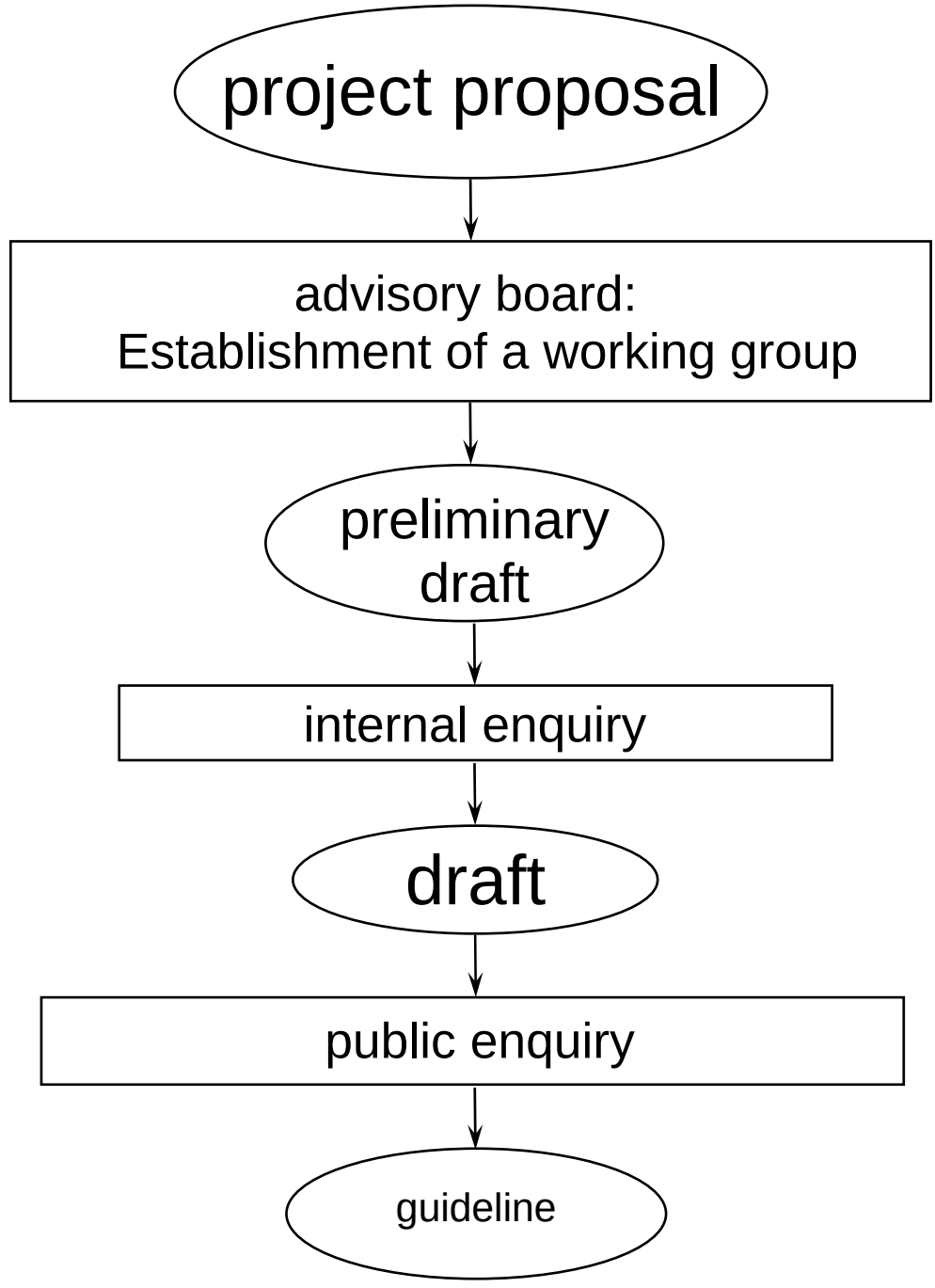
Figure 1. Simplified flowchart of the approval procedure of a technical standard



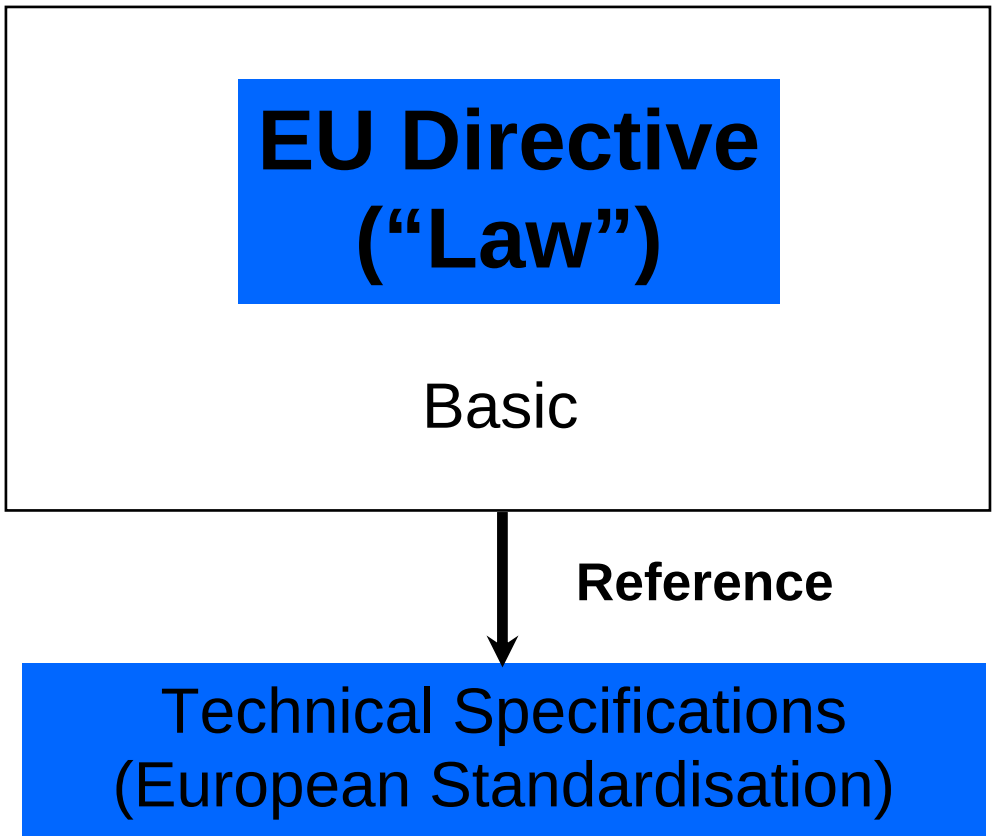


Figure 2. European Standardisation. The "New approach"

Table 1. First VDI drafts

Working group	number	Title: Monitoring of effects of genetically modified organisms
WG 1	VDI 4330 part 1	– basic principles and strategies
WG 2	VDI 4330 part 3	– pollen monitoring; technical sampling of pollen with the pollen-mass-filter (PMF) and sigma-2-sampler
WG 3	VDI 4330 part 4	– colonies of bees as a biological sampler of pollen
WG 5	VDI 4330 part 7	– Qualitative methods for the detection of genetically engineered nucleic acids in the environment

Table 2. Further standardisation projects and working groups

Working group	number	Title: Monitoring of effects of genetically modified organisms
WG 2	VDI 4330 part 2	– sampling for pollen monitoring
WG 5	VDI 4330 part 5	– Sample drawing of plant material to detect genetically modified nucleic acids in the environment
WG 5	VDI 4330 part 6	– Methods for extraction to detect genetically modified nucleic acids in the environment
WG 5	VDI 4330 part 8	– Quantitative methods for the detection of genetically modified nucleic acids in the environment
WG 7	VDI 4330 part 9	– floristic survey
WG 7	VDI 4330 part 10	– floristic mapping
WG 6	VDI 4330 part 11	– Molecularly ecology/soils: Elisa/BT
WG 6	VDI 4330 part 12	– Molecularly ecology/soils: soil biodiversity
WG 8	VDI 4330 part 13	– Procedures to measure effects on non-target organisms (butterflies)
WG 9	-	– Effects on Soil Biota (confirmed)
WG 10	-	– Resistance Monitoring for Bt-maize (confirmed)