Avosetta Meeting Siena Sept. 29/30, 2006

German Report (Gerd Winter)

1. Overall regulatory approach

There is one horizontal Law on Gene Technology covering all aspects of "white" and "green" genetic modification. The law transposes Directives 90/219 (on contained genetic modification) and 2001/18 (on deliberate release and the placing on the market of GMO). In addition, the law contains provisions on enforcement, coexistence and liability not predetermined by EC law. Provisions providing national input into EC procedures based on Regulation 1829/03 are laid down in a short separate law, the Law implementing Reg 1829/2003 of 2004..

Requiring authorisations and monitoring the overall approach is – as provided by EC law – to follosw the traditional direct and supervise style. Alternative instruments such as charges or tradable allowances are seen to be hardly suited to GM technology because for their employment much more risk information about GMOs than available would be necessary. The directive approach is presently about to be even perfectioned by MS experts who are working on finding thresholds for tolerable GMO loads in various environments.

Whilst in the normal case an authorisation to manufacture, release or market a GMO must be obtained in addition to product or process related further authorisations required for other concerns (such as e.g. the quality of a GM seed, the performance of a GM pesticide) with regard to medicinal products the "one door one key" – principle applies, i.e. the risks from genetic modification is checked together with the risk from chemical properties, the performance etc. of the product. Work is going on in order to introduce one door one key also in other areas. All this is or will however be determined by harmonised EC law.

No authorisation is required for the placing on the market of products containg GMOs if the content of GMOs is not higher than 0,5 %, the presence of GMOs in the product is accidental or technically unavoidable, and other conditions are fulfilled.

2. Executive competencies

The Land authorities are responsible for **contained use** of GMOs. The Bund is involved in so far as a federal expert committee (Zentrale Kommission für Biologische Sicherheit –ZKBS) must be heard in the authorisation procedure concerning the construction of installations and the working with GMOs.

Bund agencies are responsible for the **release** of GMOs and (insofar this is not an EC competence) the bringing on the market of products consisting of or containing GMOs.

Concerning the release of GMOs the Federal Agency for Food Safety and Consumer Protection (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit – BVL) is competent to issue the authorisation. Several other Federal Agencies must be heard beforehand, among which figure – concerning environmental aspects - the Federal Agency for Nature Protection (Bundesamt für Naturschutz – BfN) as well as – concerning aspects of human health - the Robert Koch Institute (RKI) and the Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung – BfR). The Land agencies whose competence is

affected must also be heard. In addition, the ZKBS must be asked to render an expert opinion. It is moreover provided that the Commission must be informed of the application and any comments from other Member State must be taken into consideration.

The supervision of the once authorised release is in the competence of the Land authorities, because they dispose of the personnel on the spot. Should any violation of laws ask for the modification or withdrawal of the authorisation this is again in the responsibility of the BVL.

Concerning the **bringing on the market** of products containing or consisting of GMOs (except for food and feed) BVL is once more competent to issue the authorisation. Several other Federal Agencies including BfN, RKI and BfR must be heard before. However, Land authorities are not involved. ZKBS is to asked to contribute an expert opinion.

The supervision of the once authorised placing on the market of products is in the competnce of the Land authorities. Should the authorisation have to be modified or cancelled this is again in the competence of BVL.

Concerning the placing on the market of **food and feed** products consisting of or containing GMOs national authorities have only the competence to comment in the procedure directed by the Commission, or they have to produce a risk assessment report if so asked by the Commission. Competent for such comments and reports is BVL, but this agency when elaborating the report is required to hear several other Federal Agencies including BfN, RKI, and BfR.

3. Deliberate Release

a) Risk assessment, risk management, precaution

The material standard for authorisation is that

(1) the operator must be a reliable (zuverlässige) person
(2) the person directing and supervising the release must have the necessary expertise
(3) it is ensured that the safety measures required according to the state of science and technology are taken
(4) effects damageable to human health and the environment are not to be expected which according to the state of science are not acceptable in relation to the goal of the release.

The fourth criterion is particularly relevant for an understanding of the precautionary principle. It apparently allows for a balancing of adverse effects with the goal of the release. The reason is that not seldomly the risk of a GMO is intricately and unseparately tied to its benefit. For instance, if a GM seed has been armoured with insecticide properties the benefit of its survival is achieved at the cost of intoxicating insects, i.e. (from an ecocentric perspective) inflicting harm on the ecosystem. For instance, GMOs that kill more parasites than necessary for the protection of the plant would be regarded as not acceptable. This balancing is however not foreseen by Art. 4 Dir 2001/18 which by requiring that "no adverse effect" will occur starts from an anthropocentric view which would not regard the killing of parasitic insects as a damage. I have argued[1] that the two approaches can be reconciled if one reads "no adverse effect"to allow for the balancing required under German law. Concerning other risks such as the transfer of the insecticide property to other organisms the balancing of

[1] G. Winter, Nturschutz bei der Freisetzungsgenehmigung für gentechnisch verändertes Saatgut, Zeitschrift für Umweltrecht 10/2006, 456 (forthcoming)

risks and benefits is by German lawyers however understood not to allow for anything else but the minimisation of such risks.

The methodology of risk assessment applied in practice follows the structure proposed in the Commission guideline. The methodology establishes a considerably high standard of checking, because it extends the assessment even to indirect risks such as the change in agricultural practices (e.g. if due to pesticide resistant plants farmers are tempted to use even more pesticides). Other questions are still under discussion. In particular, in the case that the release is planned in a protected FFH area special provisions are lacking which relate the risk assessment to the specific protection goals for the area. Moreover, it has been noted that the risk assessment guideline by no means takes the benefit side of the release into consideration.

As for risk management the licensing authority has broad powers to attach conditions to the authorisation. Such conditions mostly concern the concrete operation of the release and the self-monitoring obligations of the operator.

b) Authorisation procedure
See answer to question 2.

c) Monitoring
See answer to question 2. It may be mentioned in addition that self-monitoring is a very important tool in the risk management of GMOs. The operator must file a monitoring plan together with the application, and the monitoring requirements are fixed by conditions to the authorisation.

d) Public participation
The law and a sublegal regulation provide that the authorisation procedure is subject to a public participation procedure. The application must be put on display for public inspection, and comments can be filed by anybody. An oral hearing was foreseen in the initial version of the law but it was deleted as a requirement after experiences perceived to be too turbulent.

Access to information follows the general access to information legislation. Transposing Dir 2001/18 a positive list of information not to be regarded as trade secret was laid down. For concerns about obstruction activities at some places of release the requirement that the place of release may not be held secret has raised controversy. It is understood that the cataster number of the piece of land must be made public but not its precise address.

e) Court review
Most court decisions have thus far been concerned with authorisations for installations and works for genetic modification. Standing to sue has been granted to neighbours of installations.

In relation to the release of GMOs standing has been granted to neighbouring farmers who were concerned about cross-pollination by GM plants. No judgement has so far been rendered which found that the risk was misjudged by the authorising authority.

A somewhat queer case concerned a farmer who had bought corn seed that was found to be contaminated with yet unauthorised lines of genetic modification. The farmer was ordered not to sow the seeds and destroy them because the sowing would require an authorisation for deliberate release of GMOs. Upon his complaint the first instance court upheld the

administrative order. The second instance court upheld the order not to sow the seed but quashed the order to destroy them.

Another similarly queer case concerned a non-GM farmer whose crop was contaminated by GM pollen from a neighbouring field of a GM-farmer. An order was issued asking the farmer not to bring the crop on the market because it lacked an authorisation for the placing on the market of GMOs. The court upheld this order.

f) Penalties
Various minor violations are regarded as administrative offences. They can be punished with up to 50.000 €. The unauthorised release of an GMO is regarded as a criminal act and can be punished with an unlimited fine or up to 3 years imprisonment. Strangely enough the unauthorised placing on the market of a product containing or consisting of GMOs is only regarded as an administrative offense. This reverses the seriousness of the deed. The release of GMOs in individual cases is certainly less risky than the placing on the market because in the latter case the effect can be numerous introductions of GMOs into the environment.

4. Placing on the market
Although it is clear in general terms that for the placing on the market of GMOs the authorisation procedure under Dir 2001/18 must be applied whilst for GM food and feed Reg 1829/2003 applies some irritation exists with regard to GM seeds. In legal terms Dir 2001/18 is tenrelevant basis. The EFSA however also accepts applications for authorisation under Reg 1829/2003 also for that GM food and feed "for cultivation". 15 such applications are prsently pending. The difference of procedures is not irrelevant. Dir 2001/18 reserves the right to say no to the national authority. And even if after the EC consultation procedure the Commission has rendered a positive decision the national authority can still obstruct this because it has the competence of final decision. Under Reg 1829/2003 the final decision on the authorisation – whether positive or negative – is in any case the Commission.

a) GMOs other than food and feed
I have no practical insight into the relevant procedures but would expect that very few such procedures are pending given the fact that seeds are rather treated as a case for Reg 1829/2003.

b) Food and feed
Germany is heard like all the other MS during the authorisation procedure. The national authority responsible for risk assessment or consultative comments according to Art. 6 Para 2. lit c and Art. 6 para 4 sentence 3 Reg 1829/2003 is BVL. It renders its opinion in consent with the RKI (Human Health) and BfN (environment). Risk assessment studies and comments must be conducted following Annex II Dir 2001/18 and the Commission Guidance based thereon. Whilst RKI does normally not have objections BfN has often critical comments asking for more information or tests. This can be explained by the fact that in the RKI a "pure" scientific approach prevails whilst BfN reflects a more precautionary and even environmentalist culture. It is not foreseen that the ZKBS is heard in the procedure.

As a side-remark it is submitted for discussion that the more administrative procedures are shifted to the EC level the more the question arises if the comments fed into the process by national agencies should not also respond to demands of transparency and participation. In this context it may be interesting to note that a German Expert Commission on Risk Assessment Methodology has proposed (in 2003) that national legislation should be

introduced ensuring the coupling of international administrative practice to national risk assessment discourses.

5. Co-existence
The aim of ensuring coexistence is to preserve areas for land-use free of GMOs. This can be for the sake of GM-free agriculture (which in European terms includes also forestry and fisheries) or of GM-free natural habitats. In the first case we may speak of co-existence of agricultures, in the second of co-existence of natural habitats.

a) Co-existence of agricultures
The basis for this is Art. 26a Dir 2001/18 and the Commission Recommendation of 23 July 2003. "It is important to make a clear distinction between the economic aspects of co-existence and the environmental and health aspects dealt with under Directive 2001/18/EC on the deliberate release of GMOs into the environment." (Commission Recommendation sub 1.2.). Co-existence shall prevent the admixture of GM and non-GM production/products in order to allow for producer/consumer choice. It is not designed (although it does contribute) to protect human health and the environment. Its protected good is economical, not ecological. Its concern is not so much ecological risk (direct damage to predators and indirect damage through genetransfer to wild relatives and other species) but rather contamination of crops of the same kind which is cultivated on neighbouring fields. Therefore co-existence measures come atop of measures which shall prevent harmful effects on human health and the environment. Some measure can however serve the same goal, such as, for instance, a land register. It can be used in order to draw conclusions for both the contamination of like cultivations and the ecological risk.

Germany has introduced several measures to ensure coexistence of GM and non GM agriculture.

aa) Land Register
Implementing Art. 31 (3) (b) and No. 3.5 of the Commission Recommendation on Co-existence of 23 July 2003 a land register was established. Farmers releasing GM seeds or planting seeds whose placing on the market was already authorised must notify the BVL a specified time before doing so. A specified set of information is listed in the register. Some of the information is open for the public, including the name and specific marker of the GMO, the modified properties, and the plot of release/planting of the GM seed. It is still controversal if the exact location of the area of release or cultivation must be made known to the public the underlying concern being hooliganism.

bb) Rules of Good Practice
Rules of good practice are formulated concerning the separation of GM and non-GM products in agriculture, processing and trading activities.

cc) Liability
Although the German GMAct has established strict liability for damage from effects of genetic modification this liability is restricted insofar as it presupposes that damage is caused to human health or a real object. This excludes liability in cases where the crop of a neighbouring non-GM-farmer is contaminated without causing damage to human health or the environment on the neighbours property. Damage can nevertheless arise if the farmer cannot sell her crop as GM-free anymore or must even obtain an authorisation for the placing on the market of the contaminated crop because it is regarded as being or containing GMOs. In such case the German GM Act provides that the operator must pay compensation for the economic

loss. The observance of good pracice rules does not exclude liability. In the case of multiple causation joint and several liability applies.

This liabiliy scheme has experienced ferocious attacks from the side of the seed industry. However, they rejected a recent proposal of theMinister for Environment to set up a compensation fund with contributions from the seed industry. The Land Sachsen-Anhalt has filed a complaint of unconstitutionality of the scheme at the federal Constitutional Court.

In practical consequence the liability scheme has probably much contributed to the fact that farmes are very relunctant in using GM-seeds.

dd) GM free zones
GM free zones have been declared in several German agricultural regions but only as a matter of voluntary commitment. There is presently no legal basis for binding rules preventing the nuse of GM seeds in specified areas. It has been suggested that landscape planning, a non-binding guidance tool, could be used to better coordinate agricultural practices.

I believe the introduction of binding rules carefully specifying GM-free zones would be compaible with EC law. The decisions of the Commission and the Court of First Instance on the Oberösterreich regulation would not necessarily contradict this. The Commission, supported by the CFI, discussed the restriction established by Oberösterreich as a further-going measure in the sense of Art. 95 (5) EC. This is not of interest here. Sedes materiae is rather if the EC legal acts regulating the authorisation provide full harmonisation or leave space open for national legislation. It is arguable that they do not leave space for restrictions extending to whole regions in the political sense. But they do so in relation to valuable sites in the geographic sense. If so national measures of nthis kind are not preempted. This implies that they are not measures in the sense of Art. 95 (5) EC.

b) Co-existence of natural habitats
In contrast to agricultural co-existence co-existence of natural habitats has not yet been much debated. The preservation of GM-free habitats and species could be based on different policy considerations, such as

- the ecocentric quest for preserving pristine areas
- the dominant political will of societies and their reflection in political decisions of democratic governments
- the need to preserve non-GM reference areas for long-term monitoring of GMO-impact.

Looking for a legal basis for such foundations it could be argued that the Habitat Dir 92/43 by constructing nature as a common heritage of mankind adopts a kind of ecocentric view. But this is doubtful because the thrust of the Direcive is sustainability, hence nature as used by man. Nevertheless, I believe Art. 6 para 1 of the Directive by requiring the laying down of protection goals allows for discretion of MS to define specified areas as GM-free. This would mean that it is up to the authorities and their constituencies and political priorities if they do so.

In Germany the national and Land legeislation on nature protection can also be understood to allow for making naturals habitats GM-free. In fact, in one Land (Schleswig-Holstein) regulations establishing protected FFH areas sometimes provide that no GMOs may be introduced into the area. This covers deliberate release as well as the introduction of GMOs bearing authorisation for the placing on the market.

If a nature protection area is declared without such specification the release and planting of GM-seeds is not prohibited per se but must pass the normal procedures and criteria of risk avoidance.

In the case of deliberate release in or around a Natura 2000-site the release should be regarded as a project in terms of Art. 6 (3) Dir 92/43. This means that in the authorisation procedure the environmental risk assessment must be enriched by considering impacts on the peculiarities of the protected site.

In the case of planting GM-seeds bearing authorisation for the placing on the market a special FFH-impact study must be made in accordance with Art. 6 (3) Dir. 92/43. This raises the question whether the authorisation of the placing on the market of the GMO does not preempt national measures in relation to nature protection sites. This might be deduced from Art. 22 Directive 2001/18. But such effect would presuppose that in the risk assessment elaborated during the authorisation procedure the many different ecosystems in the EU are already taken into consideration. This is neither current practice nor would it be manageable. Therefore post-market measures related to specific valuable sites are not preempted by the marketing authorisation.