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Nano Regulation in Austria (II): Workplace Safety, Industrial Law and Environmental Law

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Summary

This dossier focuses on workplace safety, industrial law as well as on environmental law (water, air, soil, waste). These fields of law are likewise influenced by EU law and are very complex due to their interlocking with Austrian law. Discussion and conclusion refer to both dossiers on nano-regulation in Austria. They tentatively conclude that current legislation covers in principle nanotechnologies, especially in those cases where nano materials/nano products endanger legal interests. Existing knowledge gaps, the brisk and to some extent unforeseeable development of technologies and their wide range of applications (often across all disciplines and thus across all fields of law) will in some fields lead to specific alterations (sporadically as well to legal reorientation) in order to guarantee an adequate risk and innovation management.

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Introduction

This dossier continues the overview given in Dossier 018 on legal provisions applicable in Austria with regard to nanotechnology. The emphasis is put on the one hand on provisions in relation to workplace safety, and on the other hand on industrial as well as environmental law. Workers are among the first which are exposed to potentially hazardous nanomaterials and nano products. Workplace safety provisions serve as a legal basis for their protection. To cover emissions into the environment, several provisions can be deduced from industrial as well as environmental law, which serve the protection of human life and health, and the environment (especially the three environmental media water, air and soil).

Workplace Safety

Due to the increasing manufacturing of nano products and usage of nanomaterials and nanotechnology, as well as due to the insecurity in connection with potential hazards[1], the need for protection of workers has been gaining significance.

Of central importance for the protection from exposure to nanomaterials in the workplace environment are the Workplace Safety Act[2] as well as the ordinances issued in this regard (e.g. the Threshold Value Ordinance[3] or Explosive Atmospheres Ordinance[4]). Moreover, for federal employees, the Federal Employee Protection Act[5] as well as the Federal Threshold Value Ordinance[6] are relevant.

The Workplace Safety Act serves as an extensive instrument for the protection of safety and health at the workplace and obliges employers to guarantee this protection (§ 3 Workplace Safety Act). Of special relevance in this regard is the state of technical knowledge (see box) of which the employer must be aware of. They are especially obliged to determine and assess the dangers to health and security and take necessary measures to avoid work-related hazards, respectively minimize. In addition, hazards which come from nanomaterials are in general covered by these legal provisions; however, these legal obligations remain without consequences when, as in most cases, there is no knowledge concerning nano-specific hazards (yet).

The provisions contained in the fourth chapter of the Workplace Safety Act are dedicated to procedures in connection with hazardous working materials. Threshold values for such materials (max. workplace concentration values) are contained in the Threshold Value Ordinance. If necessary, nano-specific threshold values can be included quickly into the Threshold Value Ordinance. However, inflammable nanomaterials are covered by the scope of application of the Explosive Atmospheres Ordinance. A central role in the protection from exposure to nanomaterials at the workplace is taken by REACH[7], which provides for the obligation to gather information regarding the safe use of hazardous materials as well as pass it on. According to Article 32 REACH, mandatory information duties also exist with regard to non-hazardous materials in situations in which such materials are necessary for risk management.[8]

While the existing regulatory framework is suitable to deal with known dangers, workers, as mentioned above, are especially at risk in the case of unknown risks. Problems in this regard are not at the regulatory level (at least not within the framework of workplace safety provisions), but in practice. Especially insufficient procedures regarding the measurement of exposure to nanoparticles shall be mentioned, as well as the question of adequate measurement metrics, the insecurity whether current protection measures are even suitable for nanoparticles and the insufficient knowledge concerning the actual exposure and missing specific workplace measurements. However, existing gaps in these areas are probably better dealt with in laws with regard to materials rather than in workplace safety laws.[9]

Of similar relevance with regard to workplace safety are different guidelines and recommendations concerning the handling of nanomaterials at the workplace – for example the code of conduct presented by the EU Commission on responsible nanosciences and nanotechnologies research.[10] In literature, this has however occasionally been deemed as a "barely additional" recommendation[11].

Industrial Law

Industrial installations which fall within the scope of the Industrial Code[12] are obliged to protect from health hazardous immissions. In this connection, especially the provisions with regard to industrial installations (§§ 74 ss Industrial Code) are of relevance. Industrial installations are subject to approval if they are the source of hazards to human life and health as well as property, and unreasonable nuisances can develop. Hence, an installation is to be approved in situations in which both specific immission as well as emission criteria are fulfilled. Thus, hazards must be eliminated according to the state of technical knowledge as well as the state of medical or other possible scientific knowledge (see box), respectively avoided by prescribing official requirements. Likewise, negative impacts (in this context, also on the environment) must be limited to a reasonable level. Concerning emissions, it must especially be referred to threshold limits with regard to air pollutants according to the state of technical knowledge. In the event of protected interests being at risk (for example human life, health, property, nuisance protection) official requirements may subsequently be prescribed.

For so-called IPPC-installations, *i.e.* installations which fall within the scope of the IPPC directive (EU directive "Integrated Pollution Prevention and Control")[7] and are listed in Annex 3 of the Industrial Code, there are additional requirements for approval to avoid and reduce emissions into water, air and soil. Thereby possible environmental damage shall be prevented in advance through use of "best available techniques"[13], as well as accidents avoided, respectively limited and precautionary measures taken with regard to the closing down of installations. Installations which are considered to fall within the scope are *inter alia* chemical industrial installations (*e.g.* for the production of fertilizers, pesticides, plastic or pharmaceuticals), where nanomaterials are manufactured by *chemical* transformation.

Nanomaterials are neither mentioned explicitly in the IPPC directive nor in Annex 3 of the Industrial Act. Nevertheless, there is no doubt[7] that when concerned with the chemical (and not mechanical[14]) production of such materials, the additional requirements for approval under § 77a Industrial Act find application if the specific threshold limits (industrial amount) are exceeded. Installations which are explicitly exempted from this norm are installations which merely function as scientific, development or testing installations for new products and procedures.

Seveso-II-establishments[15] – installations which fall within the scope of the so-called Seveso-II directive of the EU and which contain dangerous substances in certain amounts according to Annex 5 to the Industrial Act – must abide by specific precautionary obligations to be able to cope with major accidents. Examples of these duties which fall upon the operator are the drafting of safety reports, a safety management system and an emergency plan as well as specific reporting obligations. Despite it generally also applying to nanomaterials, it cannot be stated that it suffices to speak of an effective protection from dangers arising from nanomaterials[16]: Nanoparticles are often used, however do not weigh very much, and consequently the threshold values are seldom reached. The EU Commission has obviously also arrived at this conclusion, and thus, it is planned to revise the directive[7].

Even if neither the Industrial Act nor the relevant EU provisions mention nanomaterials explicitly, and their specific characteristics have not played any role in the drafting of these provisions yet, in principle they offer protection for health and environmental hazards which are caused by nanomaterials. However, difficulties arise from the envisioned threshold values, immission threshold limits or even generally unknown risks which might derive from nanomaterials (due to the reference to the state of technical knowledge). Possible adaptations to suitable threshold values, respectively an increase in information exchange are therefore especially relevant. Furthermore, it shall be referred to the specific safety-related provisions *inter alia* in laws regarding foods, pharmaceuticals or medical devices.

Water

Due to the increasing industrial use of synthetically manufactured nanomaterials one can assume that they have a larger input in various environmental media (water, air, soil). Hereby nanomaterials can enter the water cycle in various ways: for example, domestic sewage may be affected by textiles, detergents, cosmetics, pharmaceuticals or building materials, bathing waters by sun protection products, and groundwater by industrially manufactured or processed nanomaterials which are discharged into various water cycles, or by fertilizers and landfill leachates. While the use of nanotechnology might relieve the environment (*e.g.* energy conservation through weight reduction or enhanced cleaning and filtering systems)[17], the knowledge relevant to control risks concerning synthetically manufactured nanomaterials is insufficient and the potential dangers for the environment, especially aquatic ecosystems, are only partly explored[18].

Despite the lack of nano-specific regulations, the discharge of nanomaterials into the water cycle does not remain unregulated. Apart from the partly already elaborated substance-related, product-specific and installation law provisions, especially water law is of relevance. The plethora of general substance- and product-oriented norms governing emissions as well as quality-oriented norms in relation to immissions[19] in EU law[7] as well as in the Water Act (WRG)[20], also cover the discharge and existence of nano materials in(to) waters.

Of special interest in this regard are the industrial-specific provisions in the Water Act as well as the ones regarding the keeping clean of waters. Concerning the protection and keeping clean of waters, the legislator uses diverse regulatory instruments. Especially the public interest, state of technical knowledge, protection of aquatic ecosystems, due diligence and precautionary provisions are central in this regard.

In general, the use of water is subject to approval (§§ 9, 10 WRG). If the use is in contradiction to the *public interest*, and if neither statutory requirements nor incidental provisions can remedy this, then the industrial installation is not to be approved[21]. Contradictious to the public interest are, as can be deduced from the exemplary listing in § 105 WRG, for example health hazardous consequences. This would also cover damages to health caused by nanomaterials.

Technical clauses[22]: a system feature of technical regulation

Technical clauses,[23] such as "state of technical knowledge", "state of scientific knowledge", "state of scientific progress", "recognized state of technical and scientific knowledge", or "best-available techniques" are typical regulatory instruments of technology law. For example, they are used in the approval process of industrial installations and in the authorization or monitoring procedure of diverse products. Hereby the precise substantial scope of the legal requirements is not given by the law itself, but by experts (*e.g.* expert witnesses assigned to the authorities) or science[24]. Technical clauses enable the law to incorporate technological developments and progress and are used especially in those instances in which "there are no established opinions (yet) with regard to danger and safety and necessary measures."[25]

Occasionally administrative provisions include definitions on how the different technical clauses are to be understood[26], for example the "state of technical knowledge" is defined in § 12a WRG (nearly identical in § 2(8) subpara. § 1 AWG or § 71a(1) Industrial Act):

"The state of technical knowledge … is the stage of development concerning advanced procedures, facilities or operational modes based on respective scientific findings and of which the proper functioning is tested and proven. For the determination of the state of technical knowledge especially those procedures, facilities or operational modes are to be considered which are the most effective to reach a generally high level of protection of the environment in total."

In general, the state of technical knowledge is relevant in the process of installation approvals, respectively product authorizations. An obligation to adapt after approval or authorization has to be required by law or officially and explicitly ordered. Otherwise the decision of approval or authorization is legally binding and the entitled does not have to adapt to an altered state of technical knowledge. However, an example for a legal requirement to adapt an existing industrial installation to the state of technical knowledge is in § 81 Industrial Act, which stipulates that the operator of an IPPC-installation has to examine the state of technical knowledge every 10 years, and in the case of significant changes must make economically reasonable adaptations.

The state of technical knowledge (§ 12a WRG) (see box) also is applicable within the scope of the Water Act. When determining the state of technical knowledge, costs and benefits, as well as measures as a consequence thereof, are to be balanced against each other to adequately incorporate the principles of prevention and precaution. If industrial installations were to use nanomaterials and if therefore the public interest would be endangered or a third party's right infringed, then the official authority would have to take this into consideration during the approval procedure. The state of technical knowledge is also to be considered when approving wastewater discharges into waters or into an approved sewer system according to § 33b WRG, as well as emission thresholds prescribed.

The Water Act offers a wide variety of instruments for the protection and keeping clean of waters, *inter alia* general protective goals (§ 30): the health of human beings and animals shall not be endangered, the condition of the aquatic ecosystem shall be protected and improved; improvements of the aquatic ecosystem shall for example be ensured by reducing discharge, emissions and loss of hazardous pollutants as well as the ground- and spring water shall be kept in a qualitative state where it can be used as drinking water; every person has the obligation to exercise diligence (§ 31) that one's installations are to be constructed, maintained and operated in the sense of the protective goals of § 30 as well as water pollution has to be avoided. Implicitly covered by this is also possible pollution caused by nanomaterials. In instances of a risk of water pollution, there are a number of measures which if necessary can also be officially imposed; further, there are specific approval obligations for installations which are potentially dangerous (§ 31a and § 31c) as well as approvals concerning impact (§ 32).[27]

The different precautionary elements of the Water Act aim at preventing water pollution, especially by acts which, when normally conducted, would not lead to any impairments, but in the case of incidents pose a special danger to water. Installations which store and transport water hazardous substances according to § 31a are to be constructed and operated in a manner that water pollution or any other impairment is not to be expected. The term water hazardous refers to substances "which by virtue of their harmful elements…for human beings or aquatic animals/animals, especially by virtue of their toxicity, poor biological breakdown, recharge capabilities, sensorial effects and mobility, have the possibility that when affecting waters to have a long term negative impact on their ecological state or usability, particularly with regard to the supply of water".

In this connection see also the non-exhaustive list in Annex E of the Water Act on pollutants and hazardous substances.

Neither the Water Act nor the EU water provisions envision specific norms for nanomaterials – the existing laws however do in principle offer protection from water hazardous discharge by nanomaterials. As in other areas, insufficient knowledge poses a regulatory problem also with regard to water law. Concerning a possible need of reform, alongside the Water Act, especially also relevant EU provisions would need to be analyzed.

Air

For the protection of air, there are a number of regulations at the European and national level. On the national level, the Air Pollution Control Act (IG-L)[28] plays a central role. Protected resources are not only human beings, animals and plants, but also their biocoenosis and habitats, their interrelationship as well as cultural and material goods (§ 1). According to the objective targets of the IG-L, immissions by pollutants are to be precautionary reduced. The instrument provided by the IG-L, in principle, could also protect from immissions by nanoparticles.

Soil

The Austrian Federal Act on Comprehensive Protection of the Environment[29] stipulates Austria`s commitment to keep the soil clean as one measure of comprehensive environmental protection. Due to the legal competence division of tasks, this commitment was *inter alia* implemented in various provincial soil protection acts. The aim of soil protection is to ensure the conservation of soil and its natural functions to avoid harmful effects on and by human beings, animals and plants. The regulatory instruments which are used by the individual provinces for the protection of soil in principle could also protect from damages which occur due to nanomaterials.

Waste

Due to the constant increase of nano products, there is a need for danger aversion and precautionary risk measures at the end of a product's life cycle as well and therefore for suitable final storage and disposal facilities of nano products and nano-waste. The relevant waste law in this regard is strongly influenced by EU law.[7] The central norm in Austria is the Waste Management Act (AWG)[30]. Neither European nor Austrian waste laws contain nano-specific provisions. Known dangers however can be covered by the existing regulatory regime. In Austria, waste may only be disposed of or processed by installations specifically approved for such (§§ 15 und 37 AWG). The approval of such an installation preconditions that human life and health will not be endangered and that emissions of pollutants are limited according to the state of technical knowledge (§ 43 AWG). In addition, according to § 38 AWG other administrative provisions (*e.g.* concerning water, air and soil – see above) are to be taken into consideration when approving such installations as well.

Whether the protected resources water, air and soil are impaired by nano-waste is to be determined in the approval procedure by expert opinion. If harmful effects to human beings, animals and the environment are to be expected, necessary measures are to be taken. With regard to incineration installations, for example, this could be a new type of filtering mechanism or the determination of specific threshold limits. Concerning landfills, sealing measures towards the underground and the atmosphere, innovations with regard to seepage water treatment as well as separate threshold limits regarding the disposal (water solubility) could become necessary.

In addition, nano products or waste could at any time be classified as hazardous waste and included into the H-criteria (hazard-relevant characteristics of waste such as explosive or cancer-producing characteristics) by the List of Wastes Ordinance[31]. As soon as nanomaterials are included into the catalogue of hazardous waste, specific consequences would be set in motion such as the so-called surface landfill ban, special approval requirements, special abilities of the waste-operator as well as mandatory records and notifications. Moreover, existing H-criteria (such as carcinogenic effects of substances) could also lead to the circumstance in which nano-waste, even without explicitly being included into the H-criteria, could be regarded as hazardous.

However, a safe and consequent consideration of dangers and risks deriving from nano-waste is complicated by far-reaching nonlabeling on the one hand, and by existing knowledge gaps on the other. Apart from a possible labeling obligation (which should differentiate between loose and consolidated nano-particles), it would also be thinkable to consider the final disposal already when discussing safety concerns at the manufacturing and marketing stage. It could be possible to construe a liability of the polluter as already exists with regard to motor vehicles, electronic devices, batteries and packaging. It would be worth considering waste disposal facilities which are specifically approved for nano products. However, it remains problematic in this regard that even if one had a continuous labeling obligation, at the end of a product life cycle it would often not be determinable whether one was dealing with nano-waste or not.

Discussion

This, non-concluding, overview over the Austrian legal situation regarding nanotechnology in NanoTrust dossiers 018 and 019 shows that the development of nanotechnology takes place in a legally and actually highly complex environment. The reasons therefore are numerous.

For one, nanotechnology, as an enabling technology (as is micro-electronics), extends to various fields and spheres of applications. Apart from the considerable amount of diverse legal provisions, even so-far well-defined individual sectors such as the law concerning medicinal products or medical devices cannot offer an adequate legal framework basis for cross-departmental nanotechnological developments (*e.g.* nano-sensors used in the medical sector). Extra difficulties in achieving an appropriate regulation generally arise from the speed of technological developments and in this regard the insufficient knowledge.

Further, the increasing influence of European law (and of international law) plays a dominant role. The interconnection of national law, which possesses a highly regulatory character, with the far more innovative European law results in an additional increase of complexity of the matter: hence, national law, by confrontation with partly totally new regulatory instruments, organizational structures and procedures, is under strong pressure to adapt.

The development of Austrian nano-regulation strategies evidences this complex environment. The beginnings of the regulatory efforts evidenced largely tentative efforts and often resulted in references to European law. The Austrian Nanotechnology Action Plan could lead to a change of direction. While action plans, as well as strategy papers in general constitute the beginnings of policy and regulatory efforts in the EU (as is the case with regard to nanotechnology[7]), in Austria action plans are only seldom used in the parliamentary legislative procedure. Thus, the Austrian Action Plan, in its function as a central document, could assume a structuring and orienting role concerning nano-regulation, as it identifies, combines and systemizes task fields. Apart from reducing the complexity of the matter, the Action Plan could also lead to an interconnectedness of the concerned participants and offer important impulses for further steps to be taken.

The Action Plan and the present dossiers, similarly to what has been attested at the EU level, show that: the existing legal framework in principle is sufficient to control known hazards of nanotechnology. However, the various fields of application are equipped to different extents to deal with possible nano risks: for example, the laws on chemical and medicinal products also include environmental matters; but the laws on medical devices as well as general product safety law usually do not include such matters. It is probably best to make legal alterations at the EU level due to the strong interconnectedness with European law. In the near future, this will especially concern threshold limits, authorization procedures in connection with substances, labeling provisions, legal information instruments as well as control mechanisms.

Conclusions
(Dossiers 018 and 019)

A desirable extensive examination of the domestic legal framework for nanotechnologies is still pending. Due to the strong influence from international, in particular EU law, an increased Austrian collaboration in international and European matters is necessary. Because of the Single Market, national efforts seem unpromising. According to preliminary legal analysis and due to increasing regulatory activities on EU level, it can be maintained that the existing regulatory framework is basically but not entirely suited to deal with potential hazards and risks of nanotechnology. The fact that environmental concerns are lacking in current legislation is problematic. In addition thereto, the increasing shift of risk management to private companies is likely problematic for small and medium-sized companies.

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