

Navigating German permitting requirements to build and operate a commercial scale biotech production plant

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This whitepaper is a practical guide for the acquisition of legally required permits in Germany. It is not a legal opinion. It is essential to acknowledge that every project is unique, and the complexities of process development and legally required permissions cannot be fully captured in a single document. Each state (Bundesland) in Germany has its own government. Laws, Regulations and policies also change with time. This means that the required permits and the responsible authority will vary from state to state. State-, project-, and site-specific requirements must therefore be confirmed by the applicant. It is recommended that users consult with qualified experts and conduct their own thorough analysis before making decisions or taking actions based on the information presented in this document.

Executive Summary

This whitepaper serves as a practical roadmap for companies intending to construct and operate a large-scale biotechnology production facility. The focus is on the Federal imissions law (BImSchG), planning and building law, water law, major-accident law, genetic engineering, occupational and chemicals law, and customs and tax matters.

It has been compiled after referencing the abovementioned German laws and conducting extensive interviews with experts in the field of legally required permissions for building and operating industrial processing facilities in Germany.

- For large chemical-biotechnology production facilities, an early assessment is normally required to determine whether authorisation under section 4 BImSchG in conjunction with the 4th Federal imissions regulation (BImSchV) is required. Classification depends on the process, substances, capacity and ancillary installations.
- The BImSchG permit consolidates many, but not all, approvals (concentration effect). Water-law permits for uses of water bodies, infrastructure planning approvals, and genetic-engineering permits fall outside the concentration effect. Infrastructure planning permits are consolidated in its own concentration effect under the administrative procedure act (VwVfG).
- The main source of delay is usually formal and substantive incompleteness. Pre-application consultation, an application conference, an agreed expert-report matrix and robust change control are therefore decisive.
- For BImSchG procedures, the current enforcement handbook states three months for the simplified procedure, seven months for formal procedures for new installations and six months for formal procedures for material changes, calculated from formal completeness; extensions are possible.
- Water-law procedures are site- and use-specific. Separate permits are required for abstraction and direct discharge; prior coordination with water management, nature conservation and fisheries is expressly recommended.
- Where genetically modified organisms (GMOs) are used, the biosafety level and whether notification, registration or authorization applies must be clarified with the state authority. Responsibilities differ by state.

Core message

The fastest robust route is not a linear series of authority contacts, but an early coordinated multi-track procedure:

- *secure site and planning law first*
- *clarify BImSchG leadership*
- *run water permission procedures and genetic-engineering permission procedures in parallel*
- *freeze technical evidence early and control changes rigorously.*

Quick Decision Logic

Question	If yes	Immediate action
Is the land zoned for industrial use?	A development plan/industrial area can materially reduce risk.	Check zoning plan, area type, required facility dimensions, access, and existing contaminated land.
Does the main or ancillary installation fall under the 4th BImSchV?	The BImSchG procedure becomes the lead approval route.	Agree on the competent authority and procedure type in a pre-meeting.
Industrial Emissions (IE) installation or Environmental Impact Assessment (EIA)-relevant project?	The Baseline Report (for soil and groundwater), Best Available Techniques (BAT) assessment, and potentially an EIA report become central permitting documents	Begin preparation of the substance inventory, assess soil and groundwater relevance, and initiate EIA screening.
Are dangerous-substance quantities under the 12th BImSchV reached?	Lower- or upper-tier duties; possibly a safety report.	Calculate maximum inventory and aggregation rule; establish safety organization.
Direct water abstraction or direct discharge?	Separate water-law permit.	Agree water balance, receiving water, treatment, monitoring and ecological aspects.
GMOs in a contained-use system?	Separate genetic-engineering procedure.	Clarify biosafety level, installation, project leader and biosafety officer.

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1. Procedural structure and strategy

The concentration effect, under section 13 of the BImSchG, provides a very helpful single point of contact for acquiring most of the needed permits. Specific exemptions are permissions for water use and for the use of GMOs. Municipal consent remains a separate internal administrative participation step even where the building permit is concentrated. Under the concentration effect, the state authority for the BImSchG will act as the central point coordinating public decision procedures also for building permits (where this is covered by state law), operational safety (BetrSichV) permits, hazardous materials (GefStoffV) permissions, environmental protection decisions, etc. It is therefore, quite practical, to contact the relevant immission-control office early in the project timeline (before the end of the piloting and demonstration phase).

The BImSchG defines a few interesting procedural options which may be useful in certain cases. These are listed in the following table.

Section	Application
4	A new permit for the construction and operation of an installation requiring a permit. This is the standard route normally applied for a new major installation.
8	A partial permit for a severable part of the project. This can enable early implementation, but requires a favourable overall assessment.
8a	An early start of preliminary construction before the final permit is granted. This is done at own risk, because this permission is revocable and comes with a duty to restore the area to the condition before work started or to compensate for disturbances.
9	A preliminary binding decision can be made regarding individual conditions or site issues. This is useful for critical legal or site questions that arise earlier on.
10	A formal procedure (G = Förmliches Genehmigungsverfahren) which includes public participation. This normally applies to larger projects that require an EIA and/or may carry a risk of a major-accident.
19	A simplified procedure (V = Vereinfachtes Verfahren) which requires no regular public participation, and offers a three-month statutory decision period starting as soon as the permitting authority has determined that the application is complete in form and content.

Which permits, when and where

Already **after completion of the conceptual design**, it should be reasonably clear which dangerous substances are expected to be used or generated in the process, and how much of it is likely to be kept in inventory as a maximum. With this information, an initial EIA can be compiled. Already contact a BImSchG-responsible authority for guidance at this point.

There are several laws and authorities to be considered **during site selection**:

- Firstly, the Environmental impact assessment act (UVPG) governs the EIA. The assessment typically examines impacts on human beings and human health; animals, plants, and biodiversity; soil and land use; water; air and climate; and cultural heritage and other material assets. A site where building and operating your industrial plant may put any of these factors at risk is less favourable than a site posing no risk.
- The zoning of the site and the allowed building height, allowed structures, use, required fire safety features, etc. are generally determined by the local building authority or the municipality. Changing the zoning or allowed use is possible but difficult, time-consuming, and not-guaranteed. It is therefore generally advised to select a site of which the zoning and generally allowed dimensions already correspond well with the intended facility to be built and operated.
- Also to be considered during site selection are the facility's water needs. A site that already has a permit for water abstraction and/or discharge which covers your needs, or a site managed by

an entity that can supply water and water treatment as a service, is more favourable than a site for which these permits do not yet exist, or where natural water bodies are scarce.

- Since the authority that will coordinate the permitting process is state-dependent, it would be wise to approach this authority near the end of the site selection process but before site freeze, in case the state permitting authority points out any prohibitive factors. The process, substances, capacity, and ancillary units should be known at this point.

Once the **production organism is selected**, the GMO status, biosafety level, and requirements for contained use are known. The use of biological agents is governed by the GenTG and GenTSV, and permissions for working with biological agents are handled in a separate procedure. You must therefore contact the state genetic engineering authority for this permit.

Laws relating to occupational health and safety, such as ArbSchG, BetrSichV, GefStoffV, and BioStoffV, are to be considered when designing and/or selecting work equipment, explosion protection, and procedures for working with hazardous- or biological agents. This should be reasonably achievable around the time that **basic engineering** is completed.

Tax laws apply as soon as operation begins. It is therefore necessary to report to the customs office **before commissioning** for tax registration purposes. Earlier communication is advised to fully understand taxing structures and their implications on energy products, generation of own energy, and tax relief options.

Permitting risks and how to mitigate them

It is not uncommon to spend almost a year planning the permit application, with an additional two to three months preparing the required documents for submission. The time invested in compiling a complete and consistent application is well worth the returns when the approval process runs smoothly as a result of such a complete and consistent application package.

When communicating with the authorities, record every discussion with decisions, open points, owners and deadlines. Ask questions in consolidated form with concrete decision options. Agree expert-report scope with authorities before appointing the independent expert, especially regarding safety distance and section 29a review. Maintain one consistent data source for substances, capacity, operating hours and emissions. Mark trade/business secrets clearly and separately while providing a meaningful public version.

The table below lists the most critical risks involved in the permitting process and ways to mitigate them.

Risk and consequence	Mitigation
Unsuitable site - Planning law, safety distances or utilities unresolved	Site gate with authority/utility discussions before purchase
Incomplete documents - Clock starts late; repeated requests	Document matrix, draft review and consistency check
Moving target - Process changes invalidate reports and design	Change control board, design freeze and impact assessment
Unclear installation boundary - Wrong 4th BIm-SchV/EIA/IE classification	Early written agreement
Unviable water route - Abstraction/discharge fails ecologically or by capacity	Model alternatives: supply, recycling and indirect discharge
Underestimated inventory - Late major-accident/Ex consequences	Maximum inventory including storage, pipes and upset
Public opposition - Objections and legal risk	Early, intelligible, site-specific communication
Unworkable conditions - Cost/schedule effects after decision	Technical review of draft decision and implementation plan

2. Before applying for permits

Project Organisation

Permits will be issued to a legal entity, such as a company, a trust or even a real person. It is advised to register a legal entity, suitable for building and operation of the intended industrial production facility, before applying for any permissions. This way, site management, procurement, permits, operation, and construction can all be assigned to the same entity, thereby avoiding complications related to tax, accounting, legal documentation, etc. throughout the process.

Identify which permits are required and which authorities should therefore be contacted. Is the project an EIA/Seveso/GMO classified project? Create a map of the required permits with their responsible authorities and required proof/documentation.

It is advised to have sufficient experienced staff and to engage with specialist advisers. The following are key roles for the process of acquiring legal permissions:

Role	Minimum mandate
Project sponsor / management	Investment decision, operator responsibility, resources and risk budget
Permitting lead	Single point of accountability, authority strategy and integrated schedule
Process engineering	Basis of design, mass and energy balances, operating states and emission sources
Environment, Health, and Safety (EHS) / process safety	Hazardous substances, occupational safety, fire, explosion and major-accident concept, air-, odour-, noise-, water-, soil emissions, nature protection
Civil / infrastructure	Ground, structural design, drainage, utilities, traffic and land planning
Legal	Legal register, contracts, trade secrets
Communications	Public and neighbourhood communication

More than one role may be assigned to a single person and external advisers/contractors may also be assigned certain roles.

Before site selection, the process basis-of-design must be frozen to ensure that water needs, infrastructure requirements and required facility size do not expand after site selection. This also freezes the mass- and energy balances and HAZID, which should not change once the application is submitted.

Site selection

Do not assess a site by land price alone. The legal, environmental, political and infrastructure environment around the site must also be considered because these factors may have a significant effect on business viability.

Check the development plan, area type and permitted use. Building height, density and distances can determine site feasibility. Green-field sites without suitable industrial planning carry high risk. Consider sites with existing industry and utilities. Industrial production facilities may only be operated in areas zoned as industrial or business zones, not in residential areas or nature conservation areas. Rezoning is possible, but difficult, and may add months or even years to the timeline.

Consider distance to housing/protected receptors, air background, expected odour- and noise emissions, and traffic increase. These factors may result in stricter permit limits to protect the existing environment and infrastructure.

Consider the type and volume of water needed and emitted by the planned project. Available abstraction sources, receiving water bodies, sewer/treatment capacity, flood risk and existing water-protection areas may simplify or complicate the permit application process.

Also, the state of soil- and groundwater on the site may affect permit limits. Consider existing or possible contamination, unexploded ordnance, ground conditions, groundwater and baseline-report relevance.

An industrial production facility requires extensive infrastructure and logistics. Does the site have sufficient access to electricity, steam, gas, cooling, nitrogen, compressed air, fire water, data, rail and road, etc.? Can feedstock and product flows, storage areas, dangerous goods and seasonal peaks be reasonably accommodated on this site?

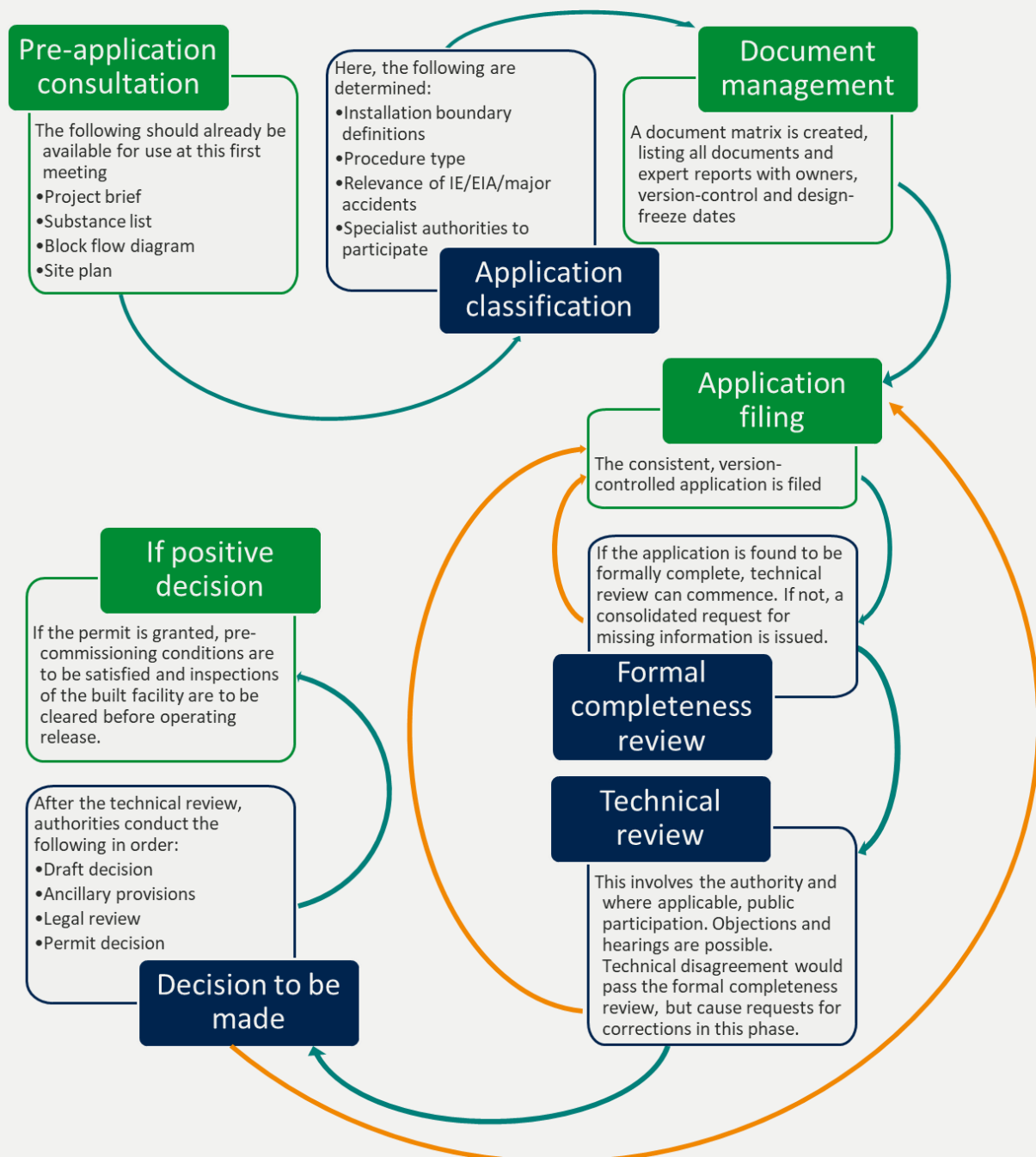
Acceptance by local stakeholders is often overlooked but non-acceptance can prove to generate significant hurdles. Engage early with neighbours, the municipality and/or industrial park, fire service, insurers and the economic ministry to build trust and gain acceptance.

For IE installations, a baseline report is relevant where hazardous substances are used, produced or released in significant quantities and contamination of soil or groundwater is possible. The baseline report contains the following:

- Complete contaminated-land and geotechnical investigations before the site freeze.
- Map of every location where relevant hazardous substances are to be handled.
- Screening of nature/species conservation, protected areas and flood risk.

3. Application documents and the procedures they undergo

A general procedural sequence of events from pre-application consultation to operating release is shown below. Notice that several iterations are often required to ensure formal completeness as well as technical clarity for the review. These are indicated by the orange arrows.



It is advised to plan a draft review before submitting the application, to minimize the required number of iterations. Reports and other documents in the application must be reviewable and consistent. After filing the application, the authorities have one month to review completeness of the application package, with a possible extension of up to two weeks. Once formal completeness has been confirmed, a

seven-month period starts (extendable by up to three months) in which the authorities conduct their technical review and after which they must issue or decline the permit. This seven-month period counts for new installations undergoing the formal procedure and includes public participation. A formal material change procedure has a six-month period, and a simplified procedure for new installations has only three months. Some reports exist of the process being delayed in particularly complex cases.

The application package

The table below lists the bare minimum of the documentation that should normally be submitted with the permit application. This is by no means an exhaustive list. Depending on the type and size of installation, the chosen site, production organism, resources and products, the risk assessment and EIA, etc. many additional case-specific documents may be required.

Chapter	Minimum content
Project and legal	Application, powers, non-technical summary, 4th BImSchV classification, procedure type, confidentiality
Site	Topographic map, plant/layout plan, cadastre, zoning, protected receptors
Process	Description, block/process flow diagrams, P&IDs, operating states, equipment lists
Substances	Inputs, intermediates, by-products, products, waste, annual quantities, maximum inventories and data
Air/odour	Source plan, emissions, abatement, impact/odour forecast
Noise/vibration/light	Sources, hours, traffic, construction phase and forecasts
Water/wastewater	Water balance, streams, treatment, separation of sanitary and process wastewater, direct/indirect discharge and stormwater
Waste	Codes, quantities, recovery/disposal, storage and routes
Energy	Power, heat, steam, cooling, waste heat and efficiency
Safety	Risk assessment, fire, explosion, major-accident and emergency concepts, appropriate safety distance
Building	Description, plans, elevations, sections, structural design, drainage, outdoor areas and escape routes
EIA/IE	EIA screening/report, BAT, baseline screening and where required baseline report

Chapter	Minimum content
Closure	Measures on cessation, restoration and aftercare, ground and contamination reports (pre-project)

4. Some elaborate topics falling both within and out of the concentration effect

Water abstraction and wastewater discharge

Water and water bodies are to be protected according to the water resources act (WHG) and the ordinance on facilities handling substances hazardous to water (AwSV). To this end, abstraction of water from any surface water body or groundwater as well as the discharge of wastewater into surface water, or into the environment in general, requires a permit to do so. Even stormwater and construction dewatering must be evaluated, and often does require water use permits.

Abstracting water from a water body can directly affect the delicate balance of nature that is dependent on it as well as other competing human activities such as fisheries. For evaluation whether a permit should be granted, the quantity of water abstraction that is required on the permit is compared to the availability of water in the specified source. The evaluation considers what effect the abstraction will have on the water body.

Direct discharge of wastewater into the environment requires certain pre-treatment and a flow and composition that can be sufficiently absorbed by the receiving water body. If the water quality or temperature of the receiving water body will be negatively affected by the incoming wastewater, the likelihood of the permit being approved is significantly reduced.

Indirect discharge of wastewater, means discharging to an existing wastewater treatment facility. This is only possible if the existing facility has the capacity to accept the quantity and load of the wastewater. Some pre-treatment may be required to achieve the incoming quality limitations of the treatment facility. Certain

by-laws may also limit the feasibility of this option.

During construction, it is necessary to dewater the site, particularly the excavated areas. This may affect the environment through draw-down, contamination migration and disposal of the removed water. For this reason, water permits may be required.

Stormwater, although it is a natural occurrence, must be managed in terms of water permit guidelines because it can wash contaminating compounds from the contained production facility into the protected natural environment. Permit requirements would include sizing of catchment and separation installations for stormwater as well as measures and limits for infiltration and discharge.

Substances that are hazardous to water also trigger water protection procedures. This usually relates to containment precautions and failsafe options that must be put in place on top of existing process containment to ensure that release into the environment does not occur, even when equipment or operating procedures fail. Prepare a waste concept covering prevention, recovery, disposal, storage and evidence.

It is recommended to involve local water management, nature conservation and fisheries when preparing an application for water use permits. Coordinate with the water authority in the district. Your permit application is to be accompanied by the intended water treatment and monitoring procedures.

The water use permits will include certain conditions and limits. Include these in your construction and commissioning planning.

Major accident law and general plant safety

The 12th BImSchV distinguishes lower- and upper-tier Seveso establishments using the thresholds in Annex I. Maximum quantities of a compound present or likely to be present must be considered; aggregation rules apply to multiple dangerous substances.

Facilities that are **not classified as Seveso** establishments are not without duties. In these cases, the duty to ensure general safety, hazardous substance management, fire- and explosion protection, and occupational safety still apply.

For **Seveso establishments (upper- and lower tier)**, duties include the following:

- Inform authorities that a Seveso establishment exists. Inform the public that a Seveso establishment exists and how they should behave in case of a major accident.
- Prevent major accidents, considering operational and external hazards and unauthorized interference.
- Provide measures against fire, explosion and release, and reliable warning, alarm, measurement and control systems.
- Ensure continual surveillance, regular maintenance, safe repair, prevention of operating error and staff training.
- Review the policy and safety management system at least every five years, before relevant changes and after reportable events.

Under § 29a BImSchG (Anordnung sicherheitstechnischer Prüfungen), the competent authority can require the operator of a Seveso establishment or a permit-required installation to have an independent expert perform a safety-related technical review and examine relevant safety documentation.

Additionally, **upper tier Seveso establishments** also have a duty to generate and maintain a safety report, emergency plans and periodic tests and training. The Gewerbeaufsicht Niedersachsen offers some [templates and guidelines on their website](#) for preparation of the safety report.

Genetic engineering and biological agents

The route for permit application for use of your production organism will depend on the responsible state authority and the type of organism (GMO vs wild type; S1 or S2; GRAS). For S1, notification may apply; for S2, registration or authorization may apply. Genetic-engineering permits are outside the BImSchG concentration effect, so you must separately approach the state authority responsible for

regulating genetic work with a separate permit application. Structural conditions for the facility follow the GenTSV. Consider these conditions and include them in the facility design. You must provide evidence for compliance through building documents and an acceptance inspection before operation. Provide at least separate project-leader and biosafety-officer functions. The qualifications needed for these roles can be verified under the GenTSV.

Chemicals law and REACH

Laws and regulations such as GefStoffV, AwSV, 12th BImSchV, REACH, and Regulation (EC) No 1272/2008 (CLP) govern substances used, produced or stored at the facility, including intermediates. Depending on the source, destination, function and volume of the substance in the process, the company would have certain roles according to CLP (Classification, Labeling and Packaging regulations) and REACH. These roles might include “manufacturer”, “importer”, or “downstream user” for example, each of which come with a set of regulated obligations.

Tax: energy, electricity, customs

Any required registration with the local customs office should occur after construction and before commissioning. The local Main Customs Office is responsible for energy and electricity tax and can inform you regarding your specific case. Depending on type and scale of your operations, exemptions, reductions or refunds may be available. Examples may include tax-free or tax reduced use of energy products or own use of electricity that is produced on site. A metering and balancing concept is required before start-up for accurate and auditable accounting.

5. Checklists

Early phase checklist

- ☐ Operating company and representation established
- ☐ Land and planning law checked
- ☐ Utility and disposal capacities confirmed
- ☐ Installation boundary and 4th BImSchV classification pre-discussed
- ☐ IE/EIA/baseline screening documented
- ☐ Major-accident inventory and aggregation calculated
- ☐ GMO/biological-agent strategy and state authority identified
- ☐ Water route pre-coordinated with specialist offices
- ☐ Report matrix, budget and schedule approved
- ☐ Stakeholder and public-communication plan available

Readiness review before filing

- ☐ Consistency - Capacity, quantities, operating hours and emissions are identical throughout
- ☐ Versioning - Date, revision and change marking on every document
- ☐ Drawings - Legible, scaled, with legends, north arrow and clear sources/units
- ☐ Reports - Based on current design; interfaces and assumptions aligned
- ☐ Public version - Trade secrets separated; non-technical summary understandable
- ☐ Parallel procedures - Water, GenTG, customs and other separate approvals scheduled
- ☐ Construction/operation boundary - Evidence separated into pre-construction, pre-start-up and post-start-up
- ☐ Organization - Owners named for requests and authority questions

Commissioning gate

- ☐ Permit decision and conditions transferred to compliance matrix
- ☐ Suspensive conditions satisfied and evidence confirmed
- ☐ BetrSichV, electrical, pressure, Ex, fire and structural inspections complete
- ☐ Safety report/policy/emergency plan final and approved
- ☐ Genetic-engineering acceptance and responsible persons confirmed
- ☐ Water-law measurement, sampling and reporting systems operational
- ☐ Energy/electricity-tax registration and metering clarified

- ☐ Operating instructions, training, maintenance and drills documented
- ☐ Management of change active
- ☐ Pre-start-up safety review complete

6. Suggested reading material

The following sources are publicly available and, at the date of issue of this navigation guideline, accessible though the included hyperlinks.

Website of the Gewerbeaufsicht Niedersachsen – particularly the major accident site

https://www.gewerbeaufsicht.niedersachsen.de/startseite/gefaherschutz/anlagensicherheit_storfallvorsorge/anlagensicherheit--stoerfallvorsorge-169910.html

and the permitting process site https://www.gewerbeaufsicht.niedersachsen.de/startseite/umweltschutz/genuehmigungsverfahren_nach_bundes_immissionsschutzgesetz/genuehmigungsverfahren-nach-bundes-immissionsschutzgesetz-52011.html

Genehmigungsverfahren nach dem Bundes-Immissionsschutzgesetz Leitfaden für Antragsteller

<https://www.gewerbeaufsicht.niedersachsen.de/download/130862>

Verfahrenshandbuch zum Vollzug des BImSchG – Durchführung von Genehmigungsverfahren

https://www.hlnug.de/fileadmin/downloads/luft/genuehmigungsformulare/VHB_Genehmigungsverfahren_-_Stand_Oktober_2025.pdf

Anleitung zur Erstellung der Antragsunterlagen <https://www.hlnug.de/fileadmin/downloads/luft/genuehmigungsformulare/Anleitung.pdf>

Erläuterungen und Hinweise für die Durchführung der Erlaubnisverfahren nach §18 der Betriebssicherheitsverordnung <https://lasi-info.com/publikationen/lasi-veroeffentlichungen/details/49-erlaeu-terung-und-hinweis-fuer-die-durchfuehrung-der-erlaubnisverfahren-nach-18-der-betriebssicherheitsverordnung>

Thank you

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