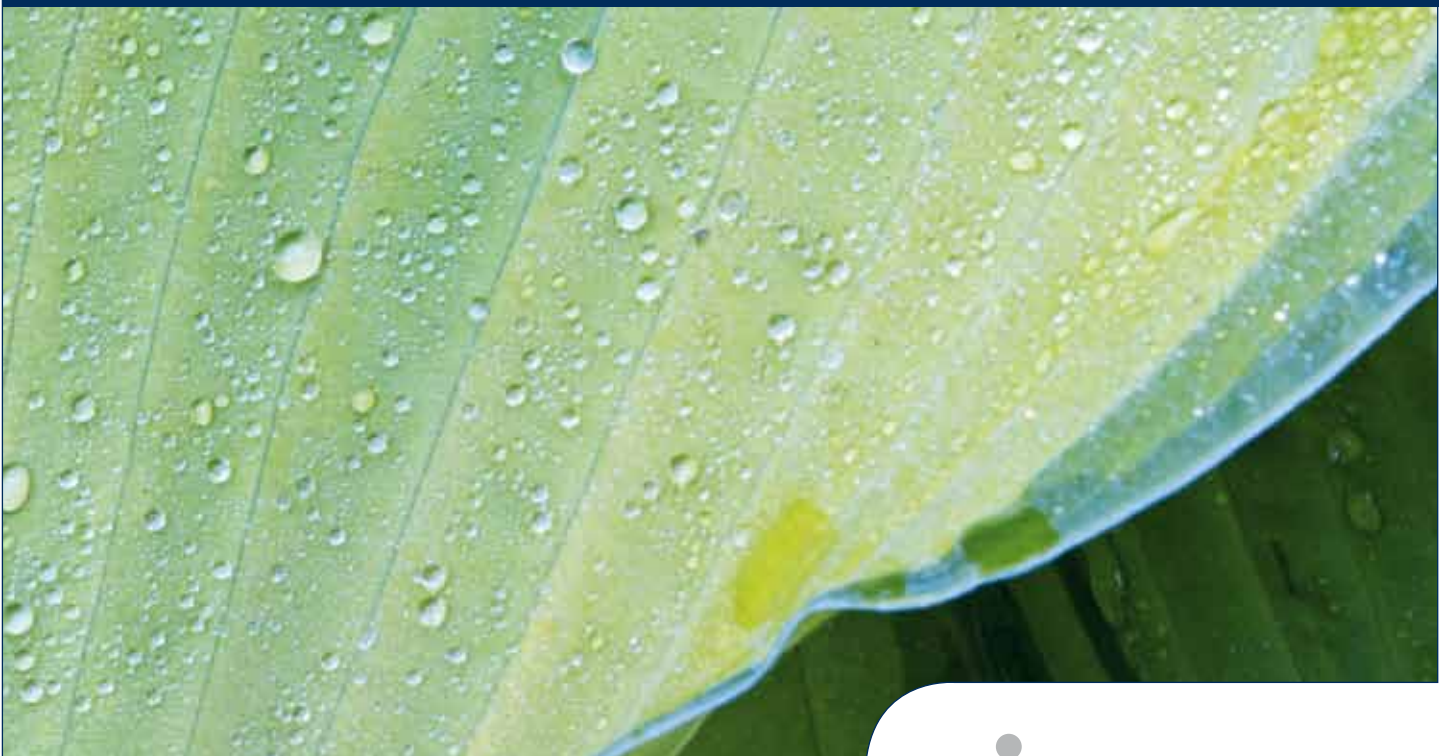




**Environment – health – safety**  
**We take responsibility**



Pharma solutions for tomorrow, today.



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## Dear Reader,

As a key partner with some of the best-known pharmaceutical and biotech companies from around the world, Vetter plays an important role in helping people alleviate pain and heal illnesses in order to lead a better quality of life. Based on the company's commitment to customers, as well as to patients, Vetter understands the critical demands of its role in the drug delivery process. Considering this, the company stays committed to a single mission: to provide customers and patients with drugs that are as safe and effective as possible, available anywhere.

Our commitment to international customers begins during the drug development phase and continues throughout the lengthy research period, during which clinical studies are conducted. At our Ravensburg and Langenargen facilities, we produce drugs and support our partners with innovative and high-quality aseptically prefilled injection systems, and also offer a broad range of other services. Our aim is to deliver the drugs to the market as safely and quickly as possible. Vetter maintains the strictest quality and security standards throughout the development and production processes. This ensures the safety of the drugs. This also benefits our customers, as they receive the approval of their drugs to the strictest official requirements in the industry.

Vetter considers its path into the 21st century, and responds proactively to an added responsibility: preserving the environment and developing healthy work conditions for all Vetter partners and employees. We have implemented a comprehensive program focused on the area of environment, health and safety, or EHS. This has allowed us to create safe and healthy working conditions that also spare resources. This contributes significantly to the highest quality and safety of our customers' drugs.

At Vetter, we believe communication with our customers is a daily responsibility. This brochure intends to inform you of our environment, health and safety program.

Sincerely,



Max Horn



Thomas Otto



Peter Soelkner

Managing Directors  
Vetter Pharma-Fertigung GmbH & Co. KG

**Internationally, Vetter is one of the leading specialists in the contract manufacturing of parenteral drugs. For over 25 years, the company has been aseptically filling drugs into injection systems for its customers using the highest quality and safety standards. As a full-service provider, Vetter supports partners throughout the world in all development and lifecycle phases of their products.**

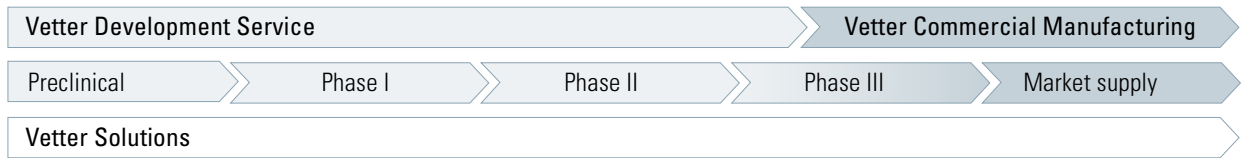




At its sites, Vetter fills innovative drugs for pharma and biotech firms throughout the world.

# Vetter and responsibility

## Vetter Services & Solutions



As a full-service provider, Vetter begins supporting its customers in the early clinical phases with its comprehensive know-how in development.



# Vetter stands for durable success

## Fostering developments

As a supplier for drug manufacturers involved with research, Vetter makes significant contributions at the juncture between fundamental research and market supply. Through Vetter Development Services (VDS), the company uses its development expertise to support its customers during the early phases of drug development. The full-service provider processes substances for clinical studies, calibrates the packaging and components with the requirements of the drug and develops the processes for commercial manufacturing early on.

Thanks to its highly qualified and skilled employees, coupled with comprehensive experience and modern project management structures, Vetter can contribute to shortening the time it takes to introduce a new drug on the market. Additionally, efficient knowledge transfer between the developing team and commercial filling supports the rapid transfer from development to production.

## Enabling long-term success

With over 2,300 employees, Vetter aseptically fills drugs for the international market according to the industry-approved standards of quality and safety. In three state-of-the-art manufacturing facilities in Ravensburg and the surrounding region, the company manufactures more than 25 drugs with the approval of the US Food and Drug Administration (FDA), and also gets approvals from Europe, Asia and other regions. Vetter's portfolio includes all of the injection systems available on the market – from vials, cartridges and single-chamber system to the company's innovative dual-chamber systems.

At its facilities, Vetter has the ability to fill approximately 400 million units per year of various volumes. With its extensive knowledge and expertise in the processing of the most diverse systems and substances, Vetter is able to give its customers the best possible assistance in all of their drugs' life-cycles: Thanks to its expertise and manufacturing capacities, the company allows its partners to set up a sustainable product lifecycle management (PLM). This supports pharmaceutical and biotech companies in achieving durable success for their products on the international market.

## Tomorrow's solutions today

The evolution of the company is closely linked with innovations that point to the future. Today, Vetter owns around 140 patents for production methods, operating media and its own injection and closure systems. These include, among others, the Vetter Lyo-Ject® dual-chamber system and the Vetter tamper-evident closure with/without needle protection (V-OVS®/V-OVS NS®). As a contract manufacturer, Vetter is continuously innovating in the area of production. In the mid-1990s, the company was one of the experts that defined the criteria for the Restricted Access Barrier System (RABS). Vetter set a trend by implementing this know-how in the area of aseptic filling in the Ravensburg Vetter South (RVS) facility. With the company's several innovations in machines and processes, the new facility earned the coveted Facility of the Year Award in the category Process Innovation.

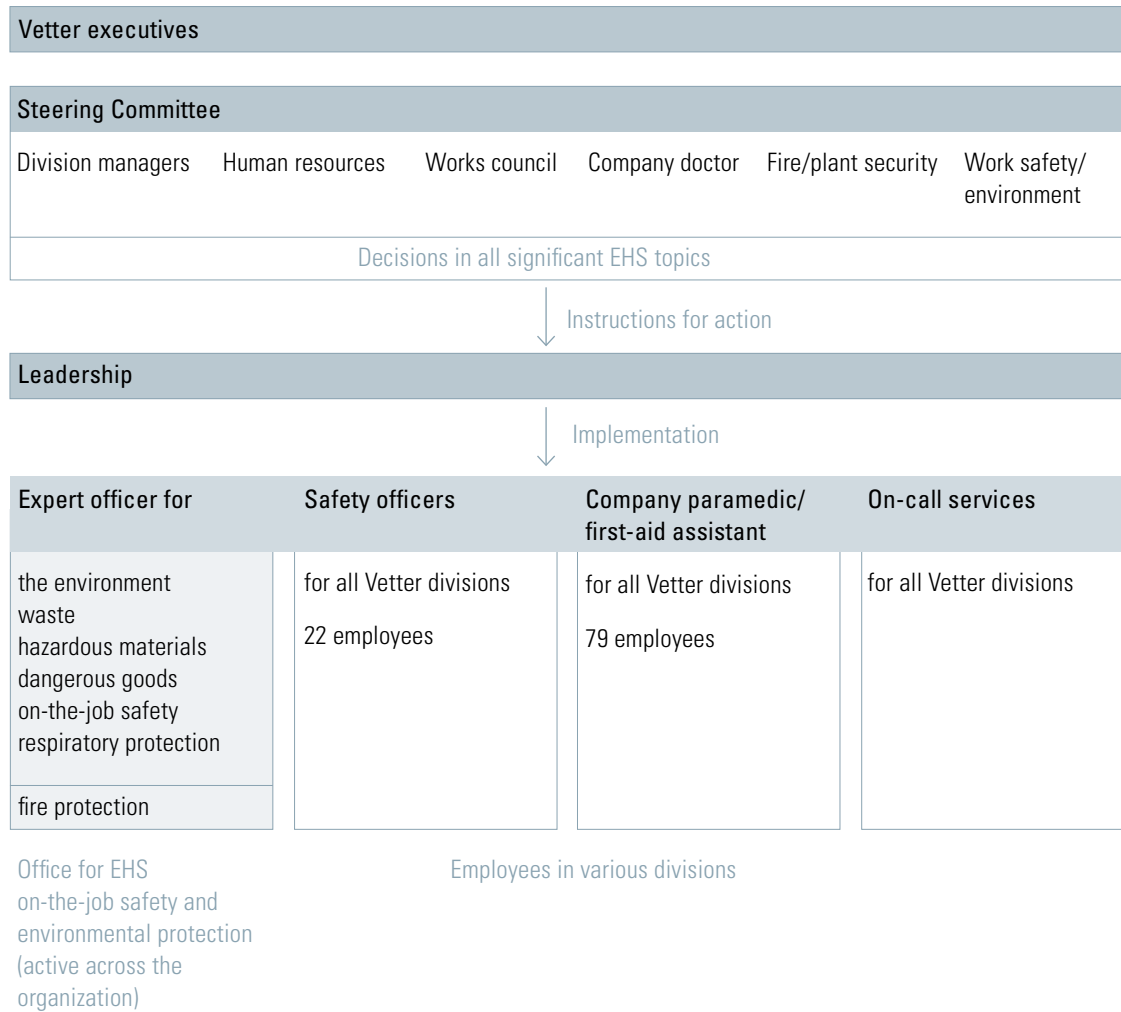
## Sustainability from tradition

Vetter is an innovation-driven company that has bridged the gap between being an operation long rooted in Upper Swabia, Germany, to a modern and globally-active service provider. While Vetter does not manufacture its own drugs, the company has grown organically with increased demands from the pharmaceutical and biotech industries.

Since its inception Vetter has steadily developed its capabilities to provide the best possible service for its customers, who are from the international pharmaceutical and biotech industries. With business operations involving drug development and production, Vetter works to continuously improve and exceed the highest quality and safety standards recognized in the industry, as well as implement comprehensive labor safety and environmental protection measures.

With its EHS strategy (environment, health and safety), which has been implemented company-wide, Vetter has put in place a broad-range program that allows safe, ergonomically and environmentally safe conditions for production.

**Responsibility at all levels: Vetter's EHS structure**



# Environment – health – safety: EHS guidelines at Vetter

As a global supplier for international pharmaceutical and biotech industries, Vetter is obliged to comply with industry-related laws and regulations regarding workplace safety and environmental protection. Moreover, our customers demand that we maintain the EHS standards. Labor protection, on-the-job safety and industrial medicine, and substance, waste and emissions management are some of the issues that Vetter monitors consistently. The aim of our efforts is seamless production and environmental management, taking both economic as well as environmental needs into consideration. A commitment to environmental protection forms part of Vetter's company principles.

## The first step: Prevention

Our safety and environmental management programs are effective in decisively reducing risks for employees and the environment. Our program is not simply designed to reduce costs related to an unsafe workplace, but rather to protect the health of our employees. That is why, in addition to comprehensive programs to create a safe workplace and to protect the health of our employees, we provide the services of a company doctor and promote health consciousness and the benefits of a healthy lifestyle to our employees.

## Responsibility at all levels

In line with our responsibility, Vetter has implemented the appropriate EHS structure within the company (see company structure). We have formed a Steering Committee composed of experts who have drafted comprehensive EHS policies, which define all of the company's preventive and corrective measures.

Vetter's senior management is responsible for the implementation of these measures in the various divisions and facilities. They are supported by the expertise of a full-time officer of the Work Safety & Environmental Protection staff division. Employees from the different operative divisions are directly involved in the execution. They receive appropriate training to act as safety officers, company paramedics, first-aid assistants and on-call officers.

## Internal and external audits

At Vetter, we recognize the importance of using natural resources wisely and conservatively. We make sure that our facilities, products and production methods comply with statutory requirements and customer demands for the efficient use of resources.

In addition to internal controls, we identify potential improvements in our EHS system and ensure that it is effective and also conduct regular audits by property insurers and customers. The results from these audits serve to continuously improve our processes and systems.

## Protecting resources is everyone's business

Vetter management expects that all employees act cooperatively and perform their part in supporting the company's efforts. New employees are given extensive information about the company's guidelines and goals. Employees from all divisions are consciously integrated directly into the processes. This is the only way for us to achieve our goals of steadily coming closer to optimized protection of labor, health and nature for the public and the environment.

**“Health is not all there is, but without health there is nothing.”  
Arthur Schopenhauer**

**Health is the core focus of our business. Each employee at Vetter directly or indirectly contributes to the health of people. Committed to its leadership role in the healthcare industry, Vetter continues to maintain good health practices in the workplace for its employees.**



# Health management at Vetter

## Responsibility down the line

Proactive health advancement is an important component of Vetter’s corporate culture. Vetter is dedicated to the well-being and good health of its employees just as the company is committed to the millions of patients around the world.

Our health program “aktiv & gesund” (active and healthy) relies on specific health management and durable fostering of health that goes well beyond the prevention prescribed by the company doctor. Just as we take responsibility for the health of millions of patients around the world through our work, we also carry responsibility for our employees. The “aktiv & gesund” program intends to specifically create healthy working conditions and support the health of individuals through preventive measures. The program is broadly geared toward employees – anyone can take part in the actions.

The health management consists of two pillars: health-conscious behavior and conditions that support healthiness, that are implemented through clear and systematic processes in which the employees are involved, as well as targeted measures and undertakings in the company.

## The scope of health management

Health management is divided up into four areas of activity:

- Work and health
- Prevention offers
- Group-specific offers
- Company medical services

The program gives employees the possibility of doing something for their own health during their working day.

“Work and health” involves factors such as designing a workstation that supports a healthy lifestyle, or adapting working conditions and designing work schedule models that are good for health and family life. This area includes the procurement of, and decision regarding, work appliances.

Work and health	Prevention offers	Group-specific offers	Company medical service
Work safety	Sports events	Reintegration interview	Physicals
Working conditions	Flu jab	Fit for the future health days	Medical examination
Flexible work schedule models	“Get fit for spring”	ErgoFIT	Eye tests
Working materials	Culinary week	Physical activity break VI	Stool samples
	AKTIV courses	Psychosocial network	Skin protection concept
	Lectures on the Campus		Statutory insurance check-ups
	Health day		



### Care for everyone

The preventive care program includes health-promoting measures throughout the year; these include “Get Fit for Spring Time” and numerous other fitness and physical activities. As part of the preventive program, employees also have access to discounted fitness club prices, sporting activities such as bicycle and running events, free flu shots and health lectures. The aim of these offers is to promote activities before any health issues arise.

In addition, there are group-specific offers that are geared toward the individual employees or employee groups. This area includes support processes in the case of illness and crisis situations, and activities for reintegration after recovery. Vetter has a professional psychosocial network in place for crisis situations as well as for addictions, psychological disorders, burn-out, stress and the aftermath.

The “fit for the future” campaign includes health days that are organized for apprentices, where active breaks also form part of this campaign. An example of this campaign would be a physical activity break that was introduced in the Visual Inspection division, where employees monitor the filled injection systems for purity and integrity with the naked eye. The visual check of the filled systems requires a lot of concentration. Consequently, experts conduct stretch and strength exercises, which help in releasing any form of tension. In addition, employees receive individual recommendations for the ergonomic installation of their workstation.

### Company doctor and first aid

Vetter’s internal doctor’s service includes the consultation, examination at hiring and statutory check-ups by trade associations, and work-related preventive examinations. The medication assessment and first-aid care are also included in this field.

Vetter places great emphasis on professional first-aid care, as it provides assistance quicker in the case of a work-related accident.

The first-aid structure has therefore been set up in a way that 11 company paramedics and 68 first aiders can be deployed in an emergency. They are equally dispersed throughout all of Vetter’s facilities and buildings.

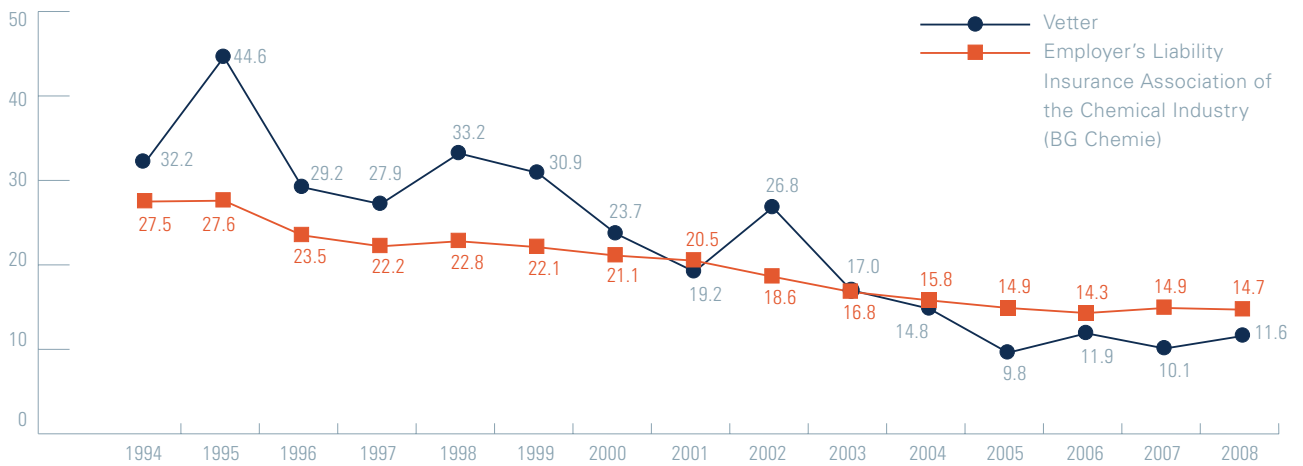
In an emergency, the paramedics and first aiders working in the building are informed by a first-aid paging system. Moreover, the specialist for on-the-job safety and the company medical service are informed as well.

To provide first aid in the event of cardiac arrest owing to ventricular flutter, all facilities are equipped with defibrillators.

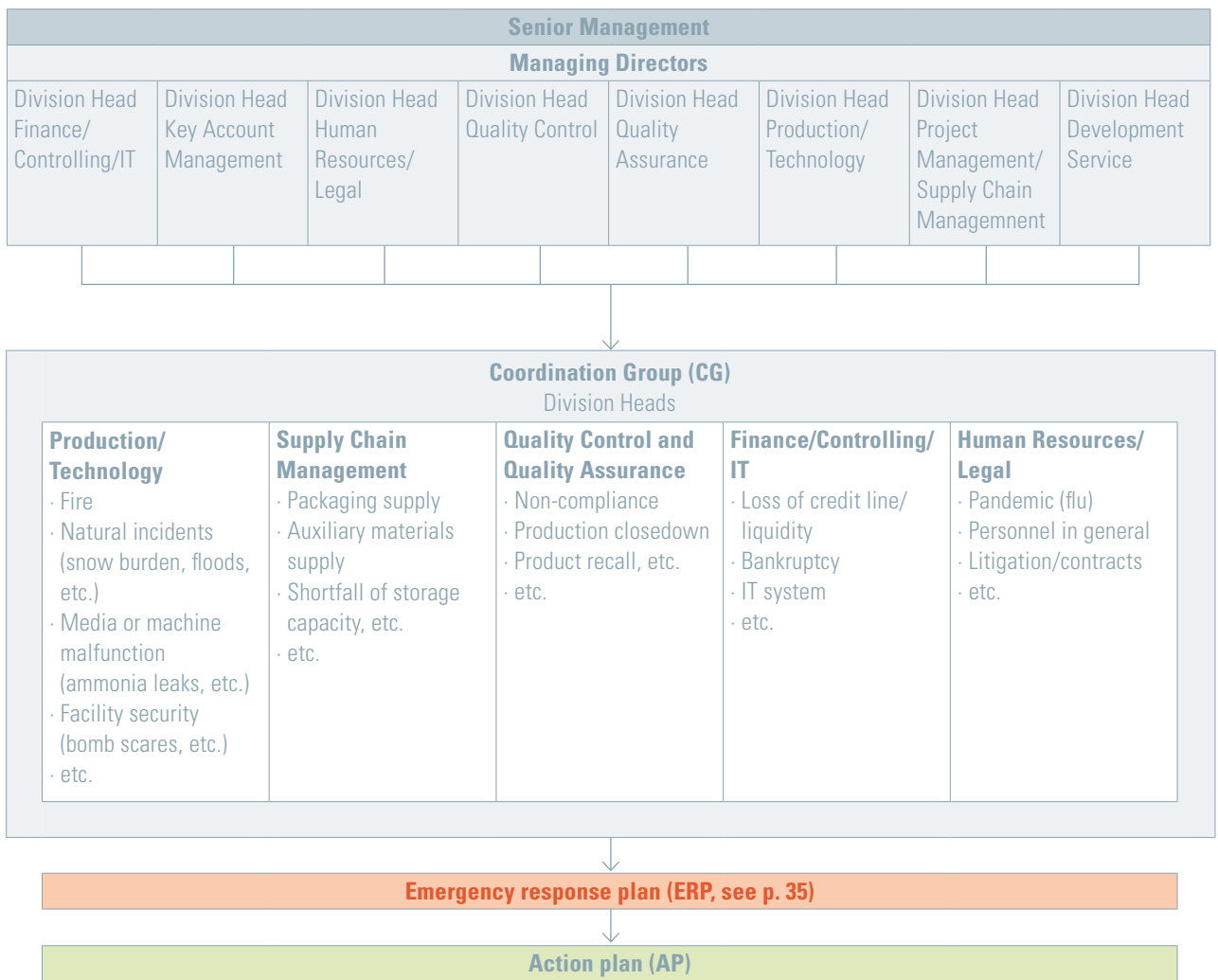
**Two factors are crucial for a good on-the-job safety concept: Avoiding loopholes in planning and good implementation. Vetter has put in place comprehensive safety measures in all areas for the protection of staff members. A corresponding training concept ensures that the regulations are not only known, but are also being complied with.**



**Work accidents/1000 employees**



**Emergency taskforce organization**



# Goal of work safety

**The safety and health protection of each employee at the workplace are the highest priorities at Vetter. This is the reason we have formulated the following goals in the field of EHS (environment, health and safety):**

- The measures in place for work safety are there to guarantee the safety and protection of the health of employees.
- Prevention and compliance of the safety processes are intended for the continued improvement of the safety and health protection of the employees.
- The rate of accidents at all locations is to be reduced to zero.
- The quality of training regarding work safety and health protection is to be continuously improved.

## **Emergency management**

Appropriate emergency plans have been devised for certain emergency scenarios, such as fires, work accidents, snow weight and the leaking of hazardous substances.

Potential incidents have been subdivided into operative and strategic threats as well as emergencies/dangerous incidents, crisis/disasters, and plotted on the so-called emergency action plan (see figure). The plan establishes exactly who is to be informed in case of unforeseen events and what procedures are to be followed.

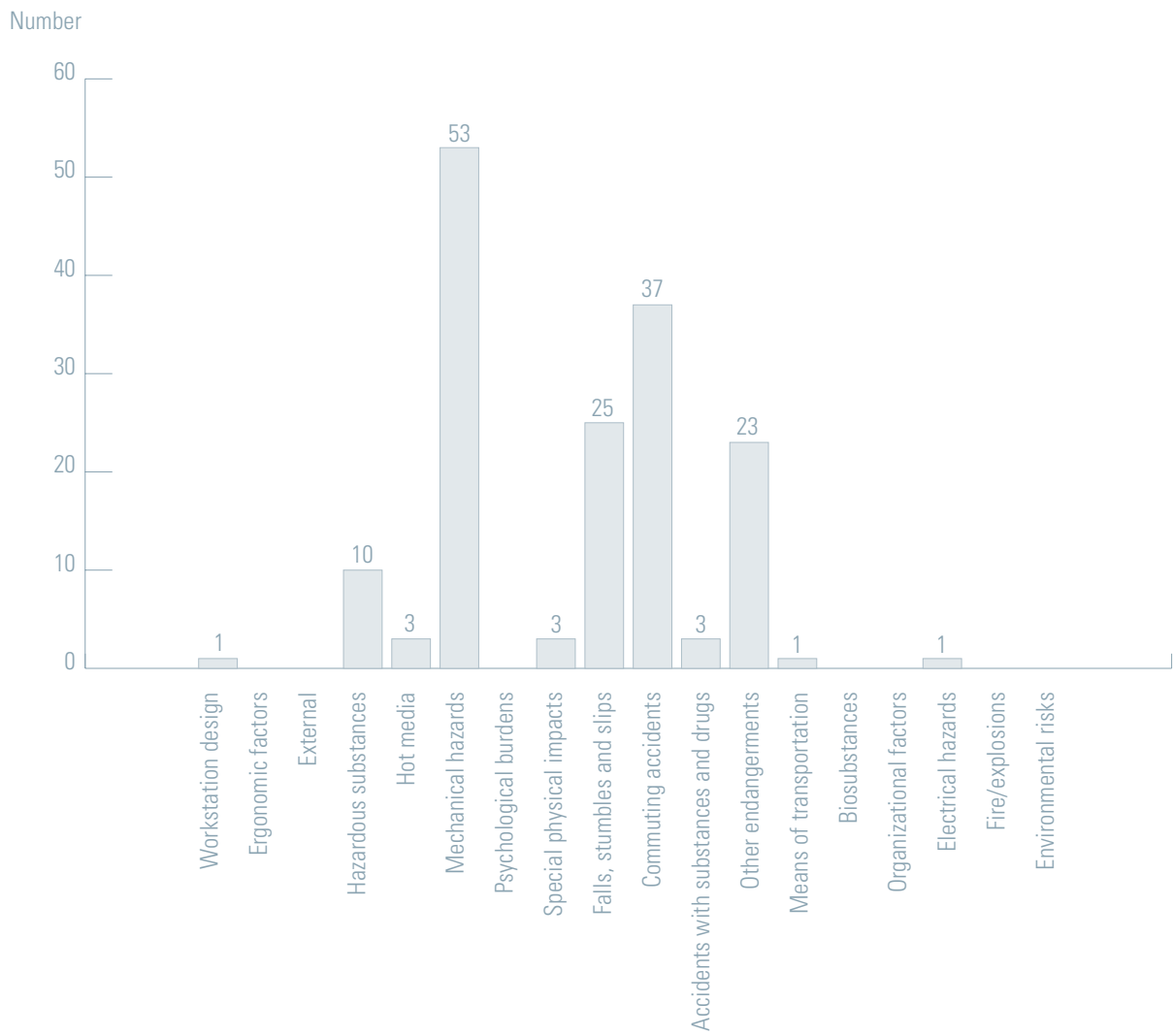
## **Work accidents**

We have focused our efforts in work safety specifically on the avoidance of on-the-job accidents. In this way, each accident is systematically categorized. After the incident, and once first-aid measures have been applied, an analysis of the accident is carried out. The details of the incident are ascertained and the source of danger is evaluated and eliminated. The aim of this approach is to avoid a comparable workplace incident in the future by implementing proper protective measures. The procedure for carrying out effective medical care in the event of workplace accidents has been described in detail in the standard operating procedure, SOP.

The proven organization, the defined safety processes and the uncompromising work in the field of prevention have contributed to lowering the average number of incidents at Vetter in comparison to the figures of the German Employer's Liability Insurance Association of the Chemical Industry, BG Chemie, the official accident insurance carrier for the chemical industry and related branches.

The main source of accidents is unconscious activities, such as slipping or getting injured while climbing stairs. Accidents that are typical in the pharmaceutical industry – injury owing to hazardous substances, drugs, etc. – are occurring at a negligible rate owing to continuously improved safety measures and training.

Risk categories 2008



Vetter employees are trained to be especially careful when handling substances.





## No hazards with proper handling

### Hazardous substances

Many of the substances used, such as the solvents and a certain part of the excipients and auxiliary materials, must be classified as hazardous materials because of their properties. Classification of hazardous materials is done according to endangerment properties and is regulated by the Hazardous Substances Ordinance. Vetter is in possession of the hazardous substance directory, which comprises the dangerous properties, the amounts used and the degree of environmental hazard. The general map of each facility shows exactly where each of these substances is located.

For the handling of hazardous substances, the company has its own guidelines that stipulate what protective measures are supposed to be taken. These have been regulated in detail and are described in a hazardous substance instruction manual for employees.

The hazardous materials are stored at the Holbeinstrasse facility, which has received approval for that purpose and has been equipped with appropriate protective measures. Storage is done according to the fundamental storage concept of the German Chemical Industry Association (VCI). A prohibition on storing materials together is being complied with.

### Biological substances

A hazard assessment according to the Biological Substances Ordinance is carried out for the handling of biological work substances, and protective measures and rules of conduct have been devised from the ordinance. In addition, rules of conduct have been defined for accidents and emergencies.

### Assignment of executive obligations

When processes in the field of on-the-job safety and environmental protection are significantly comprehensive and multifaceted, the management of a company is under obligation to assign tasks to other persons. This ensures that all obligations are being met. Vetter has the proper regulations to delegate executive obligations to the managers so that all obligations regarding on-the-job safety and environmental protection can be administered. This significantly reduces the risk of on-the-job accidents and health risks.

### Machine and plant safety

The existing systems and machine park was assessed and signed off according to guidelines from the machine ordinance. The commissioning of new machines and systems is carried out according to the CE conformity method. Pertinent certification confirms that valid European guidelines are being complied with. Systems that require monitoring, such as pressure tanks, autoclaves, gas tanks, steam boilers and elevators, are checked by an expert at regular intervals.



Hazardous materials are stored at the Holbeinstrasse site under strict protection.

**Risk matrix**

Quality damage	Ecological damage	Material damage	Personal injury
very high	massive	> 50,000 €	Invalidity/death
high	strong	5,000 – 50,000 €	Work accident Sick leave: > 6 weeks
medium	local	1,000 – 5,000 €	Work accident Sick leave: > 3 days
low	low	500 – 1,000 €	Work accident Sick leave: < 3 days
light	light	100 – 500 €	Listing in the accident log
negligible	negligible	< 100 €	No listing in the accident log

**Maximum possible effect**

catastrophic	2	2	1	1	1	1
very critical	3	2	2	1	1	1
critical	4	4	3	2	1	1
less critical	5	5	4	3	2	2
low	6	6	5	5	3	3
insignificant	6	6	6	6	5	5

**Probability of occurrence**

- improbable
- very rare (> 1x/year)
- rare (1x/year)
- occasional (1x/month)
- often (1x/week)
- frequent (1x/day)

- 6 / 5
  - No cause analysis
  - No, or simple, measures
  - No written instruction
- 4 / 3
  - Simple cause analysis
  - Appropriate measures
  - Check need for written instructions
- 2 / 1
  - Systematic cause analysis
  - Extensive risk-minimizing measures
  - Written instruction

### Approval certificate process

All "dangerous" tasks are carried out using an approval release process. This means that any activity defined as a dangerous task may only be carried out after being signed off. The corresponding approval certificates define who may do what and when, who is accountable and what protective measures are necessary, etc.

Vetter ensures that all protagonists are informed about the different activities taking place in their surroundings.

### "Dangerous" jobs include:

1. All work with fire (welding, burning, soldering and thawing, and any task that involves the use of fire) on Vetter grounds. There are outside spaces that are designated and specifically reserved for such types of work.
2. Boarding, driving, entering, driving into and bending into vessels and narrow spaces, which demands protection against dangerous chemical substances, against asphyxiation and against unintentional starting up.
3. Work in areas with risk of explosion.
4. Work at precipitous edges (roofing work).
5. Work on pipes.
6. Work on components that carry power or pressure.

### Qualification by training

Even the most comprehensive regulations are ineffective if they are not known or enacted. Vetter conducts regular EHS training within the framework of the employee qualification system. Every new employee is informed about the security regulations at Vetter during an introductory event. The training also includes safe use of ground conveyors (forklifts) and the handling of other dangerous substances and dry ice. Other topics include the assignment of executive obligations, jobs requiring release approval as well as the use of respiratory protection devices.

### The basis of our approach: Risk assessment

Our aim at Vetter is to avoid any jeopardizing of life and health or to keep the remaining risk as low as possible. All technical, organizational and personnel protection measures are geared toward this goal and our work systems are designed accordingly.

The most important aspects are the basic risk assessments of all working areas and activities devised from a risk matrix. This involves the assessment of activities at machines and systems, activities of expectant mothers, activities with hazardous materials, workstations at screens and the handling of heavy weights.

The process of risk assessment is also regulated in the standard operating procedures (SOP). Among the hazardous factors are:

- Organizational factors
- Workstation design
- Ergonomic factors
- Mechanical hazards
- Electrical hazards
- Hazards from substances
- Danger of fires/explosions
- Biological hazards
- Special physical impacts
- Psychological burdens
- Environmental risks

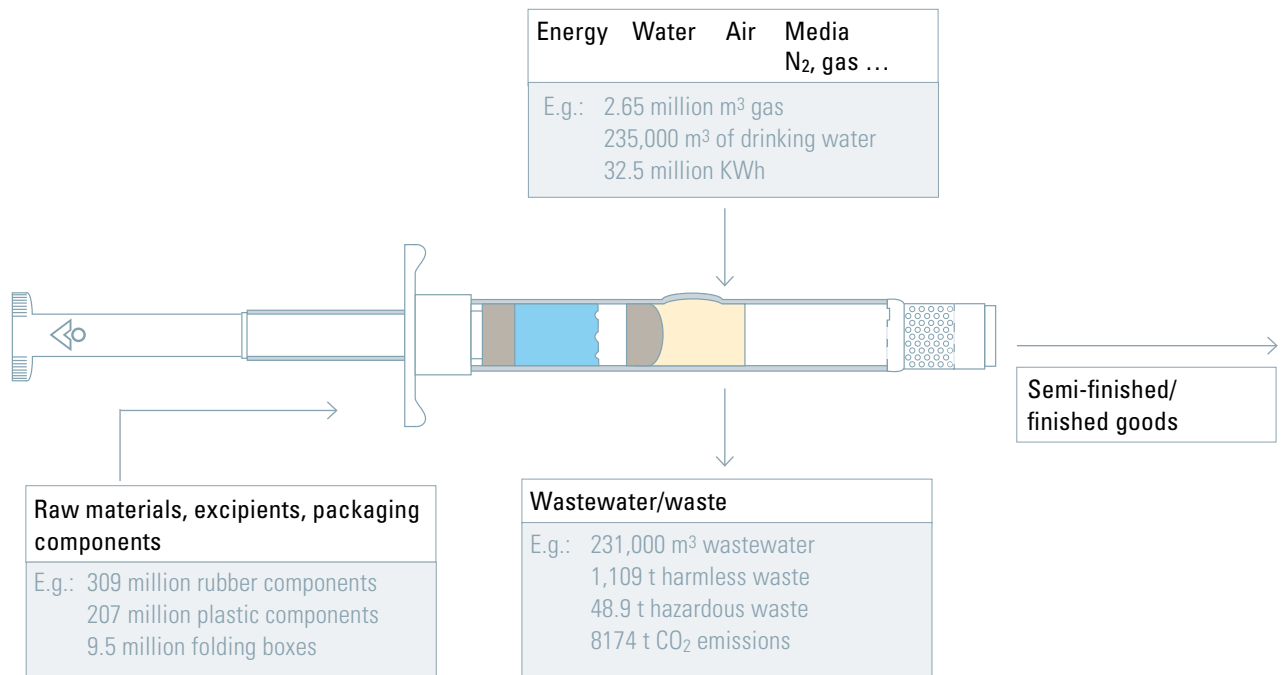
The effectiveness of these measures is controlled through regular inspections. The basis of the risk assessments complies with the specifications of the Labor Protection Law, the Hazardous Substances Ordinance, the Maternity Protection Law and the Ordinance on Industrial Safety and Health.

The risks are assessed according to the matrix (see p. 22).

**As a modern, family-run enterprise, Vetter has a responsibility toward the environment and it carries it willingly. Not only do we want to help people by contributing to their treatment with modern medication, we would also like to do all we can to actively create a world that will sustain us and our families.**



Overview of the processed materials



## Individual commitments

As a manufacturing enterprise, Vetter produces emissions, solid waste and wastewater, which is unavoidable. Thanks to regular training, each employee at Vetter is aware of his or her responsibility. By sparing the use of raw materials, excipients and energy, each individual is requested to limit the negative impact on the environment as much as possible. All Vetter's technical systems are state-of-the-art – which facilitates resource-saving work and generally increases efficiency.

Besides the use of natural resources, there are other relevant factors that can negatively influence the ecological equilibrium. Vetter takes environmentally considerate activity seriously – not only in the area of production, but also, the Vetter locations are connected by shuttle. Prior to this service, Vetter employees consumed a lot of fuel unnecessarily by driving around in their cars.

### **The legal limits to ecology**

Alas, the framework conditions established by legislators, such as the manufacturing conditions for drugs, the GMP guidelines and the Operation Ordinance for Pharmaceutical Entrepreneurs, do not allow for activity that is perfectly friendly toward the environment. Together with the technology available, the production volumes and the diversity of the production portfolio, these conditions do make for several challenges when it comes to environmental action.

### **Water: Clean and pure**

Vetter – like every other pharmaceutical company – consumes a considerable amount of water due to official standards and process steps.

Different water qualities are required for various uses, and attaining these quality levels requires water that complies with the Drinking Water Ordinance quality. The drinking water is then dechlorinated and softened in a process requiring several steps. It is then passed through a special membrane and completely desalted and hence freed of virtually all organic and inorganic substances. This so-called “purified water” is what is then used for the pre-cleaning of syringes and vessels.

The final cleaning, however, may only be done using “water for injection”. This involves purifying the clean water once again in several distillations, so that it can be used for the final cleaning and for the manufacturing of the drugs and be filled directly into the syringes.

The purified water is also turned into pure steam, which is used for the sterilization of various materials and machines. One positive ecological aspect: When processing or using the water or the steam, part of the wastewater is collected and used for other process steps, like cooling.

About 90,000 m<sup>3</sup> of water are used per production facility per year. About 85,000 m<sup>3</sup> of that water goes to the production areas as well as the technical areas that are used for the direct support of production. The rest is used for the sanitary facilities and staff rooms. All of the water is taken straight from the supply of the TeWS and the township of Langenargen.

### **Saving electricity**

Power consumption results mainly from the operation of the production facilities and the affiliated technical supply systems as well as the administrative areas.

Statutory regulations and official guidelines demand special conditions for rooms, the air exchange rate and air flow speeds for our production and storage rooms.

The necessary deployment and operation of suitable climate control systems and special air-conditioning processes, plus the processing methods used for the supply media do limit the scope of any energy-saving measures.

As independent analyses have shown, the energy-saving potential at Vetter is being almost fully exploited. This is also ensured thanks to the deployment of modern or modernized systems with the correspondingly high level of efficiency. But waste heat recovery systems, optimized outdoor air rates and heat protection measures are also broadly used to reduce energy consumption.



State-of-the-art facilities, like Ravensburg Vetter South, contribute a great deal to keeping emissions low.

#### Increased efficiency – reduced emissions

Just about all of the emissions at the company are generated by the process steam and the operating of heating plants. They consist mainly of carbon dioxide (CO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>), carbon monoxide (CO) and sulfur dioxide (SO<sub>2</sub>) from the burning of natural gas and heating oil.

The heating plants at the Langenargen and Schuetzenstrasse locations were modernized in 2005 and 2006 respectively. This means that all heating plants now attain a degree of efficiency of  $\geq 95\%$ . Thanks to these state-of-the-art heating plants, Vetter has managed to stay well below the limit values of the Energy Savings Ordinance and to reduce its emissions distinctly.

#### Consideration for the neighbors: Continuous noise reduction

Because some of our locations are in the immediate vicinity of residential areas, we have placed a high priority on taking proper noise reduction measures.

That is why extensive noise emissions measurements have been carried out at those locations. In consideration of our neighbors, we have taken steps to reduce the emission of noise more than is requested by the official noise limits, for example:

- Housing of the refrigeration system at the Schuetzenstrasse location using materials with high noise-absorption ratings.
- Construction of highly effective noise-absorbing walls at the Langenargen and Holbeinstrasse locations. These have distinctly reduced noise emissions directed toward residential buildings.

In order to reduce noise even more, plans have been drawn up to equip the safety ventilation openings of the technical facilities with sound absorbers.

### **Other ecologically relevant factors:**

#### **Use of refrigerants**

Cleanrooms must be cooled for production purposes and according to official guidelines using climate control systems. Modern refrigerators are used for this purpose. They are operated with optimal efficiency. These machines use almost exclusively CFC-free refrigerants. The few remaining older refrigerators that are still run with R22 containing CFC will be converted to CFC-free refrigerants in the wake of further optimization steps. All refrigerating systems will be operated according to the EC Regulation 842/2006 of the European Parliament and the Council of May 17, 2006 (Kyoto Protocol).

The individual refrigeration systems function as a hermetically closed system, so any leak into the environment is virtually impossible.

#### **Storage of environmentally relevant substances**

At Vetter, dangerous substances are stored in an appropriate central hazmat storage facility at the logistics center. Proper safety measures were taken in the building to protect the environment from damage:

- The floor has been tested according to the Federal Water Act
- The collecting basin is of the right size
- The electrical equipment is protected from explosion
- The rooms are properly ventilated

In addition, all of the locations have been equipped with hazmat closets for storing of small amounts.

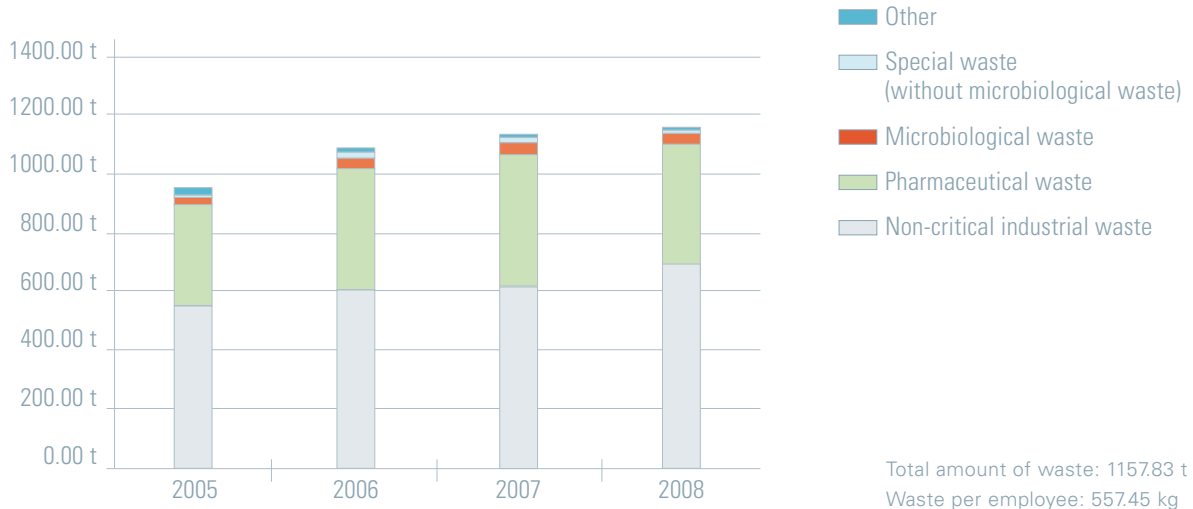
All heating oil tanks are built with double walls and equipped with a leak monitoring system. They are regularly maintained by a specialized firm and inspected by an expert.

#### **To ensure that nothing happens even in an emergency: Vetter emergency management**

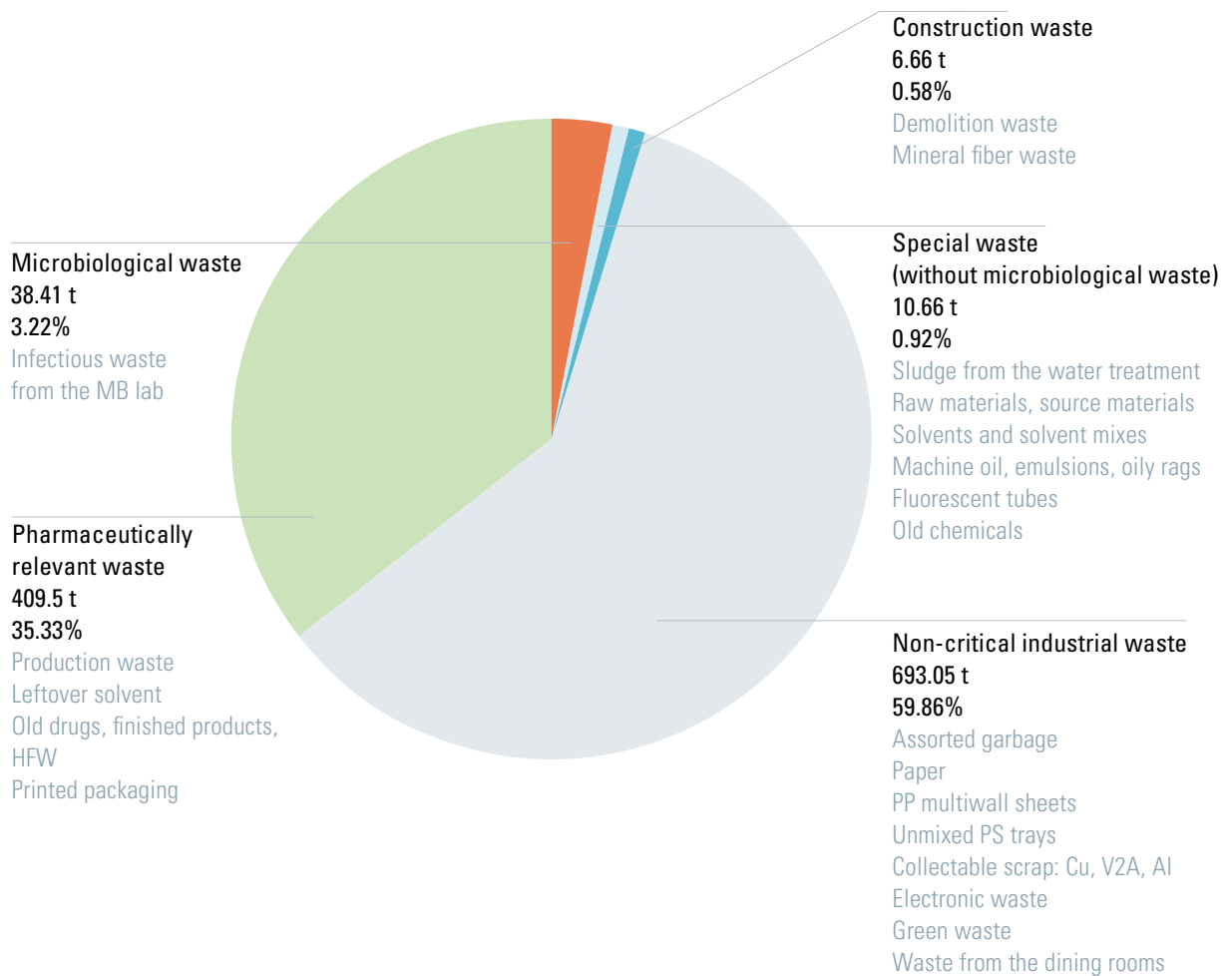
The handling of chemical substances demands a great deal of care. Nevertheless, incidents can occur, so Vetter has set up an end-to-end emergency management system. An emergency kit has been prepared with a dyking tube, absorbing materials and so on, and special manhole covers have been put in place. All employees are trained over and over again, and we conduct regular exercises together with the local fire department to test various scenarios.

**Waste development**

**Absolute waste indicator**



**Excerpt from the waste balance sheet**



# Waste disposal: Avoidance and proper disposal

**Avoiding and recycling waste is a high priority when it comes to environmental compatibility and preserving resources. Lowering the amount of waste overall is right at the top of Vetter's agenda: Following Vetter's guidelines, the employees avoid producing waste whenever possible.**

At the same time, we are constantly working on reducing the harmfulness of the waste that cannot be avoided – which is either recycled materially or thermally. Waste that cannot be recycled is thus disposed of in a manner that is compatible with the public good. The 30-percent increase in the number of units filled in the past four years has resulted in a slight increase in the amount of waste, too (see Figure). By the same token, the pharmaceutically relevant waste and the special waste (without the microbiological waste) have been proportionately reduced during the past few years.

But limits have been imposed on the efforts toward avoiding waste owing to production conditions for pharmaceuticals, GMP guidelines, the Operation Ordinance for Pharmaceutical Entrepreneurs, the sheer diversity of the product portfolio and the individual requirements of customers and products. Furthermore, the recycling of waste is not always indicated for a variety of reasons.

Of course, we use the existing systems of accepting returns, in order to return used materials, such as fluorescent tubes, old batteries, printer and fax toner cartridges and old PCs, to the manufacturers or licensing partners.

In daily operations, any waste is separated directly at the place where it is generated and then readied for pick-up at the central collection points according to the posted waste groups. Our waste disposal partners, which are all officially certified waste management companies, pick up and dispose of the waste according to statutory regulations.

## High recycling rate

We are currently able to convey over 30 percent of our generated waste as unmixed materials to a recycling operation partly at a profit, and if not, then at least at very low cost.

Some examples:

- Paper and cardboard 136.44 tons per year
- Empty trays 128.22 tons per year
- Acrylux boxes: 53.42 tons per year
- Collected scrap and precious metal leftovers

Another 40 percent of our waste is mechanically sorted by our waste disposal partners and then recycled materially or thermally.

All in all, our recycling rate stands at about 70 percent.

## Protection of the public is a priority

Statutory regulations mean that we are obliged to collect waste from our microbiological laboratories and dispose of it thermally. Protection of the public good is in fact given higher priority than the regulations concerning waste disposal.

Also in the interest of the public good, we have decided to ignore significantly higher costs and therefore dispose of primary packaging components and aqueous solutions from pharmaceutical production thermally as well. This avoids any mishandling that could be harmful to people.

All secondary packaging is taken to our waste disposal partner and crushed up mechanically before being transported to be thermally recycled.

### Reducing hazardous materials

All waste that is generated on a regular basis and is classified as hazardous is collected in special vessels approved for that purpose. If at all possible, reusable packaging is used – for example for flammable or aqueous solvents from the chemical laboratories. This waste is taken to special collection points for pick-up by the assigned waste disposal specialist.

For any first-time waste, employees are instructed to consult the person in charge of waste disposal. The latter will then classify the waste in consultation with a safety expert concerning the potential hazard. The expert will then prescribe suitable collection vessels and consult with the respective specialist waste disposal firm to define the optimal method of disposal.

Overall, the share of hazardous waste in the overall quantity of waste is relatively limited, namely less than 5 percent. This is evidence of our efforts to reduce waste as much as possible in all areas of our operations. We are constantly working toward replacing dangerous substances such as disinfectants, solvents and oils with less hazardous materials. For the well-being of our employees and the environment, we are making an effort to continue reducing this amount.

### Significant environmental aspects

With regard to the subject of waste at Vetter, there are three immediate environmental aspects that are related to our locations. On the one hand, there is the hazardous waste generated in production and in the laboratories, and on the other hand the wastewater resulting from production and from treating the process water. In addition, one must take into consideration that the Ravensburg Vetter South facility is situated in the vicinity of a water protection area. Vetter complies with the corresponding obligations. Waste disposal is performed according to the statutory regulations and strict internal provisions.

The large number of logistical processes at Vetter also have an indirect environmental impact: road transportation, generation of transportation packaging and primary and secondary packaging. However, they are not classified as significant environmental aspects. The emissions from the vehicles correspond to the valid norms.



Access road to the Schuetzenstrasse building with a gate and barrier system.

## Plant security

Besides protection of the environment and employees, protection of the customer's products, intellectual property, raw materials, production centers and other facilities also plays a significant role at Vetter. The substances we work with on a daily basis are valuable and our knowledge base is far too extensive to leave unguarded. This does present a great deal of challenges that have to be met. The factory grounds should be accessible for Vetter employees and normal delivery traffic without causing loss of time. By the same token, no one should be able to enter or leave the grounds without proper authorization. Furthermore, certain areas require additional protection, because highly valuable products or especially important and confidential information is stored there.

### Limited access

Vetter has developed a comprehensive security program that prevents unauthorized access to our facilities. The entire grounds of each facility are protected with fencing. For areas that are considered susceptible, barbed wire has been added as an extra preventive layer of protection. All entry points are secured by access control systems – this applies to the production facility grounds, all buildings as well as technical and production areas. The access control system ensures that staff members are given individual authorization to enter. Access to highly sensitive areas is strictly limited.

### Round-the-clock surveillance

The grounds surrounding all Vetter facilities are illuminated at night so they may be carefully watched. The production facilities are equipped with CCTV and a recording system. The guard service monitors the video surveillance.

### Surveillance

In addition to the precautionary measures taken on the buildings, which are continuously updated, Vetter has also contracted an external security service. This service is responsible for monitoring all production facilities around the clock, seven days a week. Furthermore, the security service monitors outdoor, building and facility controls and maintains the existing alarm systems.

All relevant processes that take place in the course of surveillance tasks are regulated by service instructions. All security personnel have undergone a prescribed training program.



## Fire prevention

Preventive and structural fire prevention is an essential component in avoiding harm to people and the environment. For this reason, Vetter has devised a broad range of measures to prevent fire from occurring. We have also guarded against fire breaking out in spite of these precautionary measures: A comprehensive concept is in place to prevent the spread of fire and smoke, to facilitate rescue efforts and to carry out extinguishing work quickly and effectively.

Close collaboration with the local fire department is very important in this respect. Fire incidents are simulated using fire drills and assessed to check if the fire prevention is sufficient. Each year, fire drills and evacuation exercises are performed as well.

Vetter's facilities are not subject to the Federal Immission Control Ordinance. In order to sufficiently protect people and the environment, a range of precautionary measures have been put in place to reduce the impact of fires.

Each building has fire access roads, which would allow the fire brigade rapid access in the case of an emergency. All buildings are divided up into fire areas and are equipped with self-closing fire doors. Wall hydrants and fire extinguishers have been installed liberally. An automatic fire alarm system with approval from the Association of Property Insurers (VdS) was installed. It provides heightened security and has a direct connection from all facilities to the fire department. It reports any incident early on.

All buildings are furnished with smoke and heat evacuation systems according to VdS guidelines. The ventilation and climate control systems can be switched off by a test chamber alarm.

A sprinkler system with a 700,000-liter tank has been installed in the storage area. The building also has a water supply and is designed as a basin. To avoid incidents in the IT area, the computing centers are protected using Inergen gas extinguishing systems.

These extensive measures have given us a safety standard that allows protection at the highest level. Our aim is to prevent a fire from breaking out, or, in case it happens, to avoid harm to people or damage to property, as well as interruptions in our operations.

# Glossary

## **Drinking Water Ordinance (TrinkwV)**

The Drinking Water Ordinance implements the EC Guideline 83/98 on water quality for human consumption as a national law. The specifications of the regulation govern protection of drinking water from contamination and guarantee that humans are able to enjoy drinking water.

## **EC Regulation 842/2006**

The regulation by the European Parliament and Council on fluorinated greenhouse gases regulates the operation of facilities with chlorofluorocarbons that promote the greenhouse effect, such as climate control systems and fire extinguishing systems according to the Kyoto Protocol.

## **Energy Savings Ordinance (EnEV)**

The regulations establish construction standards for the building and operating of buildings based on the Energy Conservation Acts (EnEG) of the Federal Republic of Germany.

## **Federal Immission Control Act (BImSchG)**

The BImSchG is the federal law for protection against environmental impact through air pollution, noise, vibration and similar processes. The clauses of this law apply to the building and operating of machines. They serve to protect people, animals and the environment from negative effects and their emergence.

## **Hazardous Substances Ordinance (GefStoffV)**

The regulation is applied when materials, preparations and products are being put into circulation, to protect employees and other persons from damage to their health and safety from hazardous materials, and to protect the environment from damage due to materials.

## **Operation Ordinance for Pharmaceutical Entrepreneurs (PharmBetrV)**

The industrial regulations for pharmaceutical companies apply to entrepreneurs and facilities that manufacture drugs and substances, and test, store and market them. It prescribes the specifications for quality assurance, training and qualification standards for personnel, hygiene and operational processes from manufacturing all the way to signing off.

## **The Employer's Liability Insurance Association of the Chemical Industry (BG Chemie)**

BG Chemie is the statutory accident insurance carrier for enterprises in the chemical industry and related industries. It makes recommendations to, and supports, over 13,400 member enterprises with a total of around 900,000 insured persons with the goal of preventing occupational illnesses, work accidents and accidents occurring on the way to and from work. It provides medical and professional rehabilitation of injured persons and makes compensatory payments. Furthermore, it schools and advises the BG Chemie management in charge of safety and on-the-job protection.

## **VdS-approved**

The VdS seal of approval is awarded by the VdS Schadenverhütung GmbH (VdS Loss Protection Ltd.) – the company that grew out of the technical divisions of the Association of Property Insurers (VdS). It is a subsidiary of the GDV (German Insurance Association) and an independent and accredited auditing and certification office for fire protection and other safety systems according to DIN, ISO and EN norms.

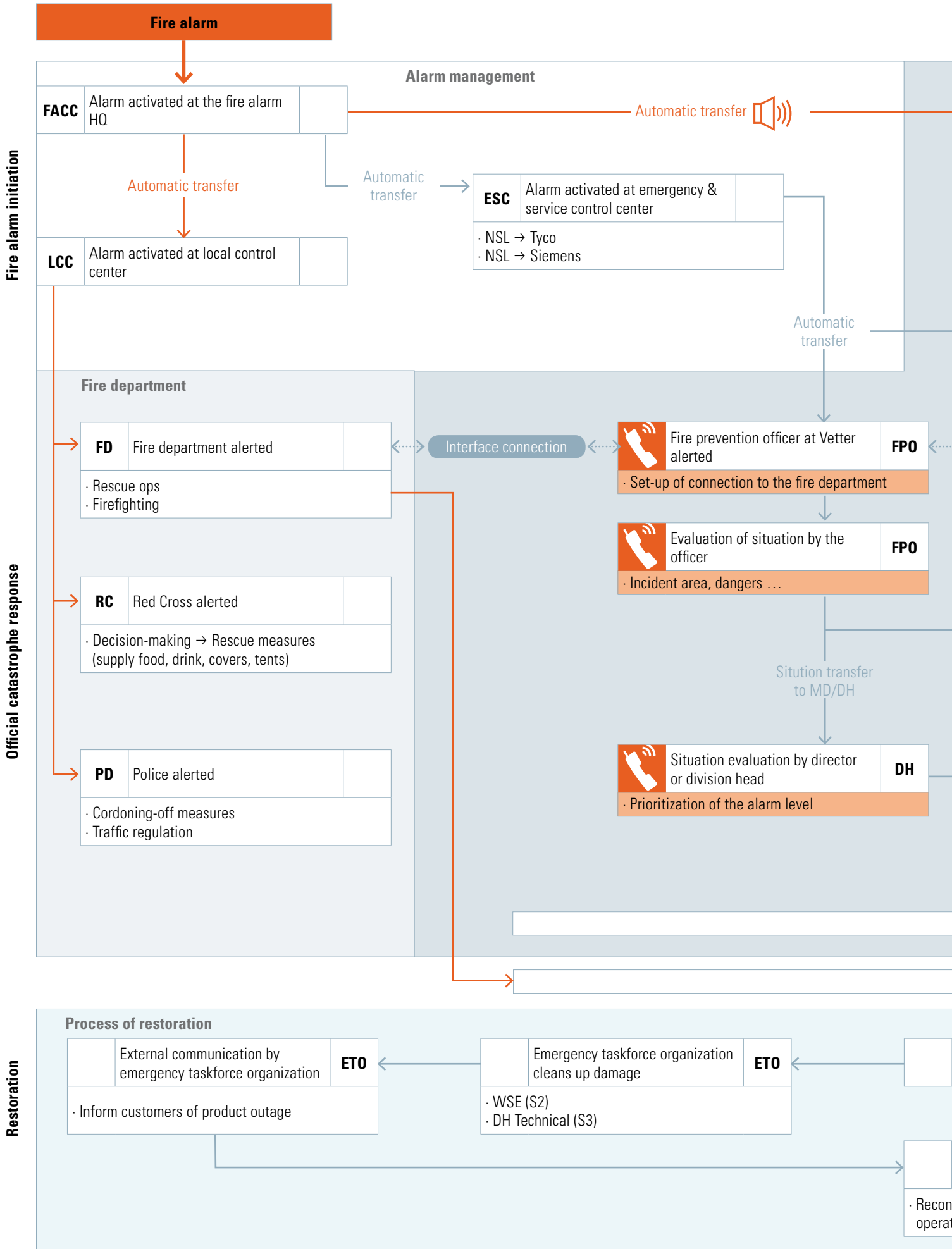
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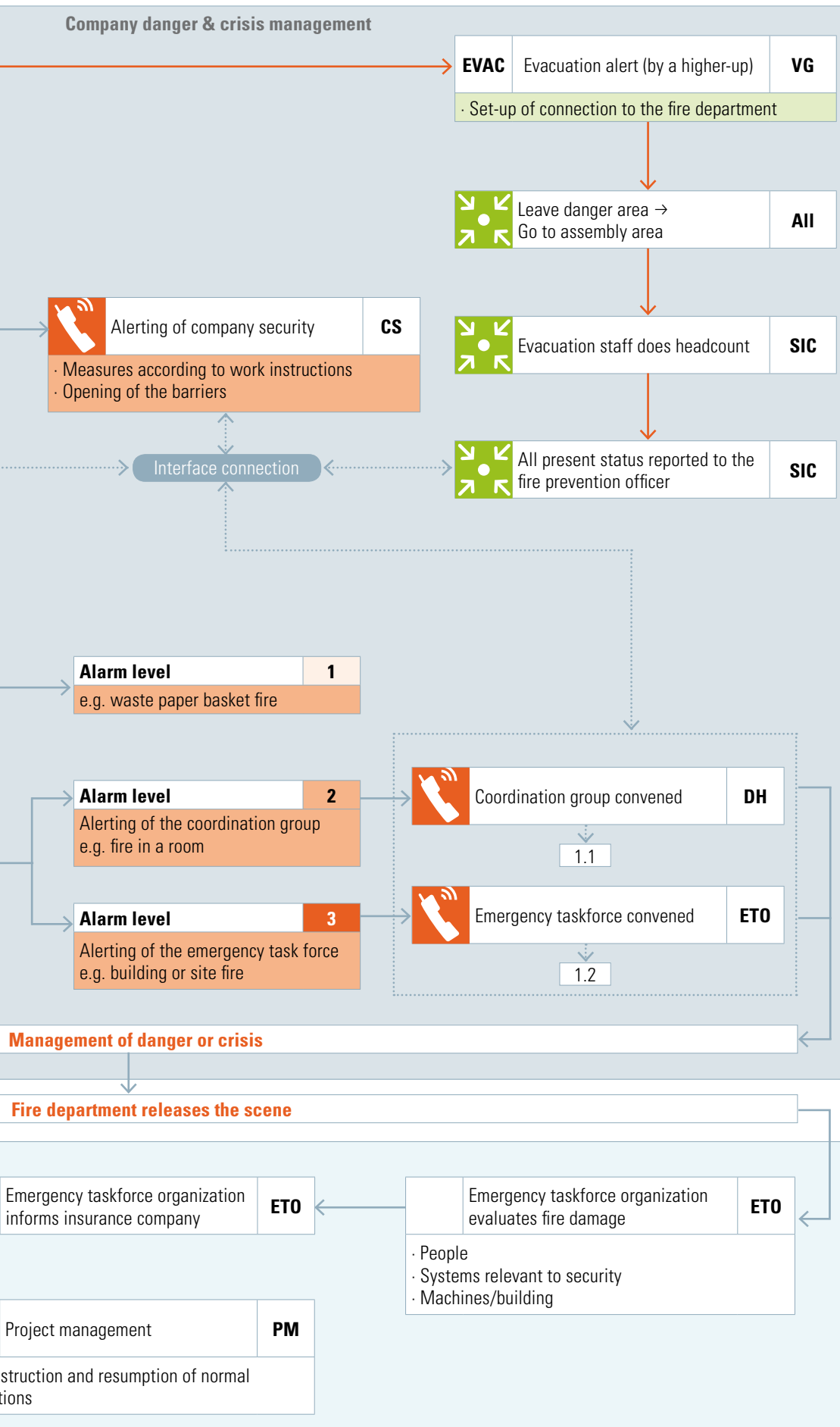
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# Emergency response plan





**FACC**

Fire alarm control center

**LCC**

Local control center

**ESC**

Emergency and service control center

**FD**

Fire department

**RC**

Red Cross

**PD**

Police department

**EVAC**

Evacuation helpers



Assembly point



Communication by telephone



Acoustic signal for evacuation

**MD**

Managing Director

**DH**

Division Head

**PM**

Project management

**ETO**

Emergency taskforce organization

**FPO**

Fire prevention officer

**CS**

Company security

**SIC**

Superior in charge

**All**

Everyone in the department

**Vetter Pharma International GmbH**

Eywiesenstraße 5  
88212 Ravensburg  
Germany

phone: +49-(0)751-3700-0  
fax: +49-(0)751-3700-4000  
e-mail: [info@vetter-pharma.com](mailto:info@vetter-pharma.com)  
[www.vetter-pharma.com](http://www.vetter-pharma.com)

**Vetter Pharma International USA Inc.**

4901 Searle Parkway, Suite 300A  
Skokie, IL 60077  
USA

phone: +1-847-581-6888  
fax: +1-847-581-6880  
e-mail: [info@vetter-pharma.com](mailto:info@vetter-pharma.com)  
[www.vetter-pharma.com](http://www.vetter-pharma.com)

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