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Contract Manufacturing of Crop-Protection Products: Some Key Considerations

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Abstract. Outsourcing takes many forms. In the case of crop-protection products, the contracting-out of manufacturing tasks requires careful thought and attention. The 1990s have seen a major change in the relationships between outsourcers and third parties. The former now demand higher 'duty of care' standards than ever before and insist on the right to ensure their implementation. Any less rigorous approach can have disastrous consequences.

Every 'Make or Buy' decision is based on an analysis of many factors and has to be part of an overall business strategy. The sourcing strategy in each phase of a product's life cycle may vary according to market needs and conditions.

Market conditions for our industry have changed considerably and will continue to do so with increasing speed. This has a bearing on production and on the question of how many assets a company is ready to finance. Excess capacity has its costs, but inability to deliver goods has even higher costs. Today's imperative for a company is to strive for maximum flexibility.

The parameters of an outsourcing strategy are clearly set by the choice of partners and the risks which the outsourcing company is ready to take.

The risk is acceptable when the partners are highly trustworthy, professional and adequately equipped. They must also have clearly defined standards for safety, industrial hygiene and environmentally sound processes which will enable quality conformance.

The choice of partner is also crucial from the point of view of liability. The other key to this area is clear and adequate transfer of know-how from the outsourcing company.

Each step of the decision-making process and the ensuing actions have to be clearly documented.

The global crop-protection industry acknowledges the risks connected to manufacturing and marketing pesticides. It has also taken the necessary steps to manage these risks. Responsible national and international manufacturers have signed the 'FAO Code of Conduct'. Today, only companies that adhere to this Code and are committed to supporting its standards can be members of the Global Crop Protection Federation (GCPF, formerly GIFAP).

In cooperation with industry and occupational health experts, GCPF has published booklets and checklists like the 'Guidelines for the safe formulation and packaging of pesticides'. These are now the accepted standards for the industry. They have been further developed into readily understood, illustrated, multilingual guidelines with very useful checklists. The former GIFAP and present GCPF guidelines have been enforced by large multinational pesticide manufacturers since 1982.

Two major events accelerated the introduction of legally binding standards:

– BENLATE 50 DF, a benomyl fungicide in the form of a water-dispersible granule, was removed from the market in 1991. The *Du Pont* product had allegedly caused more than 500 million dollars damage to nursery plants in the 1980s. It was never possible to prove the cause. BENLATE 50 DF may have been contaminated with ppm quantities of highly phytotoxic sulfonylurea herbicides. Alternatively, trace amounts of unknown by-products may

have made phytotoxicity an inherent property of the active ingredient. 'Product integrity' has since then become a major issue for the industry.

– The 1986 fire at the *Sandoz* factory on the Rhine near Basel, Switzerland, resulted in stricter regulations on marine pollutants and the handling and storage of inflammable products.

Both incident events had a tremendous impact on the companies involved and on the industry as a whole. They helped change the standards. Over the last few years, the responsibility and legal liability of the pesticide industry have altered completely in scope.

The *Du Pont* case had shown weaknesses in the process of product change-over designed to avoid cross-contamination. This had to be totally reassessed and changed.

Biologically highly active material can show effects at less than 10 g/ha. Those high activities have created a tremendous challenge in manufacturing. The allowed limit of tolerance of 1000 ppm [1], therefore, cannot be applied in every case. With some compounds like the sulfonylureas, industry is now approaching values in the region of single-digit ppm.

The *Sandoz* fire had considerable ecological consequences which led to public outcry. It also generated a spate of legal activity. Just as the Seveso disaster produced a new law on the handling of highly toxic materials, so this incident led to new standards in storing agrochemicals. Pesticide manufacturers reevaluated their operations and processes and adjusted them accordingly.

Such changes also had a tremendous impact on manufacturers' relationships with third-party contractors. The degree of responsibility assumed by the outsourcer has increased dramatically. This is, e.g., reflected in the very close auditing eye kept on contractors' operation.

Novartis was formed in 1997 by the merger of *Ciba* and *Sandoz*. Its crop-protection sector has combined the two companies' ethical guidelines in the *Carta Nova*. This charter describes the Code of Conduct of *Novartis Crop Protection*. It describes the sector's vision, business principles and dedication to product safety. The *Carta Nova* also lays down commitments to customers, suppliers, employees and the general public.

Standards like these must be ethically, socially and legally acceptable, technically state-of-the-art, and reduce the risks for manufacturers, applicators, customers and the environment to an acceptable level. If this is not done, the original manufactur-

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ers may be held liable. Turning such written standards into reality is a major entrepreneurial challenge.

Risk assessments cover all the activities within a product's life cycle. Managers and specialists review the sustainability of products and processes. They also examine outside contractors' safety and working hygiene as well as their environmental behaviour. All of these are aspects of 'duty of care'.

The application of an adequate and legally acceptable risk-assessment method is a key success factor. A good example is the risk-portfolio method of the Zürich insurance company:

The matrix shows in a clear and understandable manner the risks and degree of control in relation to the potential impact. Its use provides an indication of a company's exposure under a range of scenarios which may lead to liability or insurance issues. The priorities are visible and will lead to a guided action program.

Risk portfolios are applied both within a company and at outside factories and warehouses. They also provide a basis for authorities' own risk assessments and give managers a good overview. Company assessments are especially successful if they are carried out by a group of experts, form part of standard procedures, and become an integral part of daily working practices.

Novartis is currently striving towards a global risk portfolio which is also valid for third-party manufacturers. Risk assessment forms a basis for the decision on partnership with a particular third party. A guideline for contractors describes the steps from partner selection through to the audits made by Novartis experts.

Third-party manufacturing must in all instances be based on a written contract. This is not only good for liability reasons, but also encourages the external manufacturer to maintain standards. The contract is drafted by the Legal Department on the basis of sound professional information from technical staff. The responsibilities for outsourcer and contractor must be clearly laid down. It is very important that the outsourcing company can control third parties' fulfillment of commitments throughout the contract period.

Novartis' experience with contractors has shown that in most cases our standards, procedures, risk assessments and controls are well-accepted. Responsible pesticide manufacturers accept that they are dealing with products which need special attention and competent handling. The public knows that accidents can happen, but it would not tolerate one caused by outdated operating procedures.

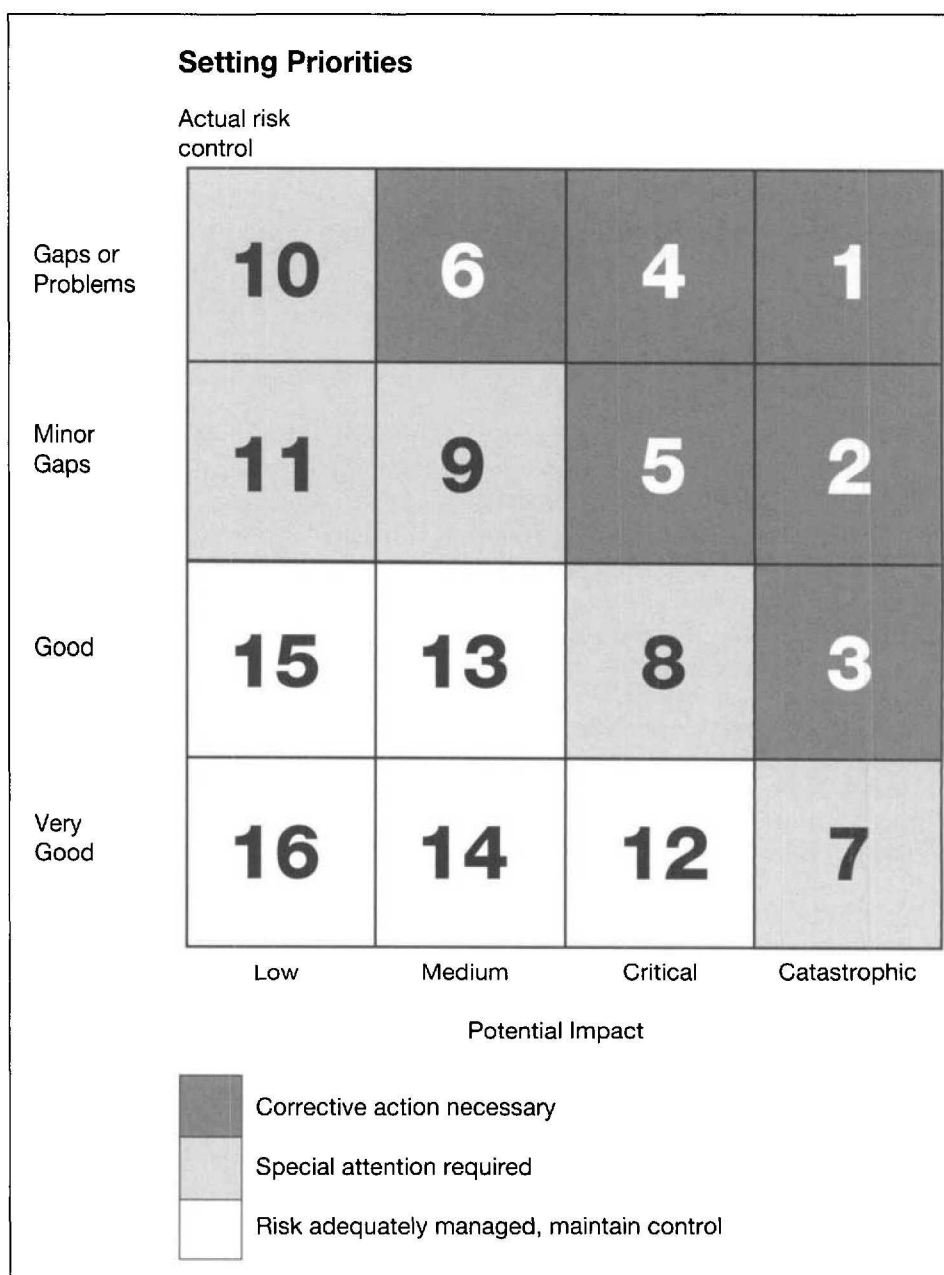


Figure. Risk-portfolio method of the Zürich insurance company

Prevention is better than cure and very often also much more economical. However, if things are not operating as planned, the contract manufacturer also has to inform the public and the authorities in the most professional way. This requires a clear information policy on the part of both outsourcer and contractor. Fast incident reporting must have high priority. The information will be much more effective if good communication has already been established. The general public must be a natural communication partner for both companies before any incident occurs.

In dealing with contractors, trust and checks go hand in hand. Rigorous stipulation and enforcement of standards are crucial. They must, however, be accompanied by a careful choice of partners willing

and able to be achieve the outsourcer's goals independently of the actual degree of auditing. Any less demanding approach may have irreparable consequences.

[1] 0.1% of an undefined by-product is the limit accepted by the EPA and EU regulatory authorities.