

MV2003.0132-gv/vam

10th November 2003

Mrs. Margot Wallström
The Commissioner for the Environment
B-1049 Brussels
Belgium

Re: Open letter to Mrs. Margot Wallström
Commissioner for the Environment, EU Commission

Dear Mrs. Wallström,

It is ironic that on the day your letter is published in the FT (November 5th) the New York Times' International Herald Tribune should run a page one story describing how a very successful Chinese pharmaceutical firm, known to supply a large number of European and North American generic firms, allegedly caused the death of several of its workers through disrespect for the Law and for the Environment.

The dramatic growth the referred company has had, and its negative impact on the Environment, can somehow be traced to EU policy - the chemical industry is well on the decline in Europe but in full growth elsewhere.

Well before REACH became news the R&D based pharmaceutical fine chemical industry was put at a competitive disadvantage as no such controls exist elsewhere. Indeed REACH being little more than the widening of existing legislation that already applies to all new chemicals in Europe, we -producers of active pharmaceutical ingredients (APIs)- have for many years needed to generate toxicology data whenever we produced amounts as small as 10 kilos of any new chemical... it is common knowledge that 97 out of a 100 products tested clinically never make it to the market - so tens thousands of products and their intermediates have needed up to \$80.000 worth of testing each - a phenomenal waste of money, rats' lives and time. Not surprisingly makers of such fine chemicals have mushroomed in the USA.

European licensing legislation, and not just IPPC (Integrated Pollution Prevention and Control), has also meant that getting a permit to build a pilot-plant in an existing EU chemical site takes longer than turning a corn field into an operating state-of-the art facility in New Jersey, USA.

The US generic industry has to thank the European manufacturers of generic active ingredients for the \$20b industry that has been created there since the 80s. Indeed the active ingredients in more than $\frac{3}{4}$ of medicines found in US pharmacies are not made in the USA, but abroad - mostly in Europe until recently. The current trend is that an increasing proportion of all US and EU generic medicines uses APIs no longer produced in the Midlands or in the valleys of the Po, the Rhone or the Rhine... but in the Far East. It may well be that this trend is inevitable, but surely we have the gnomes of Brussels to thank for the speed of the emergence of Indian and Chinese competitors.

The SPC (Supplementary Patent Certificate EU Law) has meant that the Italian and French API industry are out of the race in the process of developing and launching new generics. Some of those companies have either ceased to invest and are moribund, or they have moved elsewhere. Is it a coincidence that only one EU firm makes it to the top five largest generic firms worldwide? Countries such as Israel, Switzerland, Canada and India had no clumsy legislation to stop their companies from taking advantage of a truly global market.

The stake-holders in the pharmaceutical industry have successfully addressed the key issue on how to address a global industry - the International Commission on Harmonization (ICH) issues guidelines that apply world-wide; thus setting a level-playing field. One of the ICH guidelines that is a cornerstone of the quality of medicines in European pharmacies has now for several years been gazetted into Law in the USA, Japan, Canada and Australia - but not yet in the EU. Why? Is it to allow a repetition of the death of 80 Haiti children whose cough syrup was prepared with anti-freeze deliberately mislabeled as glycerine; an act allegedly committed by a greedy European broker? Do Europeans know that the medicines they buy in EU pharmacies can be made with APIs made in China or in India without those plants ever having been inspected by a EU authority? A situation that the FDA makes quite sure cannot happen in the USA. The Chinese producer, or its US affiliate, on whom the NYT reported on offers up to a 100 different active pharmaceutical ingredients, 18 have Drug Master Files at the FDA and 5 certificates of suitability issued by the EU's Directorate of the Quality of Medicines...

The company I run has lost millions of dollars of sales to the company in the front page story. The fact that in 1992 we, at Hovione, won a European Award for Better Environment in Industry rarely seems to influence our customers' decision-making process. Maybe now the implications of the New York Times story might lead them to re-consider.

Europe is the cradle of the chemistry, and the pharmaceutical fine chemicals industry is one of the undisputed jewels in the crown of the European Industry. With its right hand Brussels seems to do everything in its power to wreck it, with its left it wipes tears because Europe's biotech industry is lagging so far behind the USA's...

The central flaw of your policy is that you are seeking to impose regional legislation on an industry that is now global. Do you not realize that in making us un-competitive you do nothing but stimulate production elsewhere? EU policies have clearly made it harder for us to compete successfully with Indian and Chinese API producers. Sadly these business opportunities seem to lead some people that appear to have neither the technical competences, nor the ethics, nor the civic development to be involved in advanced technology industries. The consequences are dead people and deformed children.

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Are you aware that such plants are obvious dual-use installations? Are you aware that Al-Qaeda terrorists have been known to infiltrate the staff of such facilities? Do we, Europeans, not have a duty to truly protect the people and the planet by acting responsibly? Chemistry will only be safe if it is kept in competent and responsible hands. Will you please, Mrs. Wallström, look further a-field beyond your desk in Brussels; go to Haiti, go to Taizhou, and recognize that the problems you have chosen to see are nothing compared to the havoc the EU could be preventing.

Yours sincerely,

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Edgar Alexandre and Guy Villax, both of Hovione, authored in September 2002 an article on this issue;

Legislating to Death can be found in http://www.hovione.com/h_press/legislating_to_death.pdf

With copy to:

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Andrew Gowers - FT Editor
International Herald Tribune
Letter to the editor - NYT

EU legislation will safeguard trust in chemicals

From Mrs Margot Wallström.

Sir, Your editorial "Brussels discovers a better solution" (October 30) commenting on the proposal for new chemicals legislation reflects an outdated view of commercial reality. In a modern society, consumer trust in safe products is a guarantee for a successful business. We need chemicals; but the public needs to be reassured that the health risks are identifiable and small. This is what the new legislation is all about.

The chemicals reform is a test case for the principle of sustainable development. To be sustainable, any policy has to reconcile economic, social and environmental concerns.

Achieving this balance is particularly important in the case of chemicals, where the stakes are so high on all three sides. It is high time that European citizens got the high level of protection for environment and health they have the right to expect. This is why we need a new strategy for chemicals management, and we should never forget this.

The use of chemicals is an absolute requisite for modern society. They are found everywhere, from data chips to clothes, cars and carpets, and they make their way into our bodies as well. With the development of biomedical monitoring, all of us will gain a better insight into our individual chemicals susceptibility and the serious health risks linked to it. That will put an even stronger pressure for information about the chemical substances on the market, safe alternatives and safe handling.

Industry has a crucial role in this process. Continuous scaremongering about economic ruin is a sign of naivety and ignorance, with serious risks for business failure. I question seriously why the Financial Times believes we have to make a choice between addressing chemical residues in babies and polar bears on the one hand and safeguarding a fertile business climate on the other. We need of course to do both. I also tend to believe that chemical industries facing huge liability claims because of their unsafe use of dangerous substances wish the proposed system had been in place a long time ago.

We have therefore to put on the table legislation that prescribes how industry is to provide the necessary information allowing it and its end users to deal with chemical products in safe ways and look for safer alternatives.

The measures and scope that have been detailed in extensive consultation with all stakeholders, including industry, are entirely in line with what we announced in the white paper on chemicals reform two years ago and the cost estimates are roughly the same as then. In designing the system we have paid particular attention to the need to allow the important European chemicals industry, particularly the many small to medium-size enterprises, to enhance competitiveness, without compromising environment and health concerns. This will safeguard the trust in the European chemicals industry and their products, providing both a competitive business edge and benefits for the health of our citizens.

**Margot Wallström,
European Commissioner for the
Environment**



Joseph Kahn/The New York Times



The New York Times

The Hisun Pharmaceutical factory in Taizhou, China, is accused by neighbors of toxic dumping and by employees, like Shen Yunxiang, left, of unsafe work conditions.

Chinese success smells less sweet at home

By Joseph Kahn

TAIZHOU, China: The first thing that struck Shen Yunxiang when he descended into the bowels of Hisun Pharmaceutical was the smell, or rather the lack of it. It was as if the sewage system had been scrubbed with ammonia, leaving only a sickly sweet aroma strong enough to overpower the stench of human waste.

In less than a minute, though, he realized that the company had exposed him to something far more noxious than feces. He had been sent, unwittingly, to release chemical runoff that Hisun had collected haphazardly beneath the factory, possibly to avoid

paying fees to dispose of toxic waste.

Shen's chest constricted. His breathing grew labored, his head faint. Then Feng Huaping, his brother-in-law and fellow migrant worker, who had climbed down first, gasped, "Grab my hand, get me out," before collapsing in a puddle of muck.

Shen was the lucky one. He emerged with migraines and lung congestion, and doctors are still trying to diagnose the illness that is causing them. Feng died that night. A third migrant worker, Tang Dejun, also died in Hisun's fetid plumbing after he was sent down to finish the job the next day.

Hisun is one of China's leading ex-

porters of pharmaceutical products, certified by the U.S. Food and Drug Administration and the European drug commission to sell lifesaving anti-tumor and cardiovascular medications for prices Western manufacturers cannot match.

But the company may pay more attention to fighting cancer in the West than to protecting the health of its own workers and neighbors in Taizhou.

Hisun declined to answer detailed written questions about the incident, as did the police in Taizhou. But a local government official confirmed the deaths, which occurred in August, and said they were the subject of a con-

tinuing criminal investigation. The official said he did not know the cause of the deaths.

Hisun has sprouted quickly, growing from a tiny state-owned drug-maker to a pharmaceutical and chemical conglomerate. But company employees and local residents say that it has never stopped dumping untreated chemical waste around Taizhou, and that it has minimized or ignored the harmful effects of poisonous substances on its own workers.

"They were reckless to send us down there without protection," said

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Source from = Herald Tribune

Source date = 5th November, 2003

CHINA: Dangerous place to work

From Page 1

Shen, now recuperating in a nearby hospital. "To send another guy down the next day is beyond belief. They have no regard for human life."

China's economy is growing faster than any other. But the air and water in many of its leading cities rank as the dirtiest in the world, and the number of people who die at work, 11,500 through the first nine months of this year, is far disproportionate to workplace fatalities in other countries.

Much of China's economic boom has stemmed from foreign investment and international partnership. Hisun itself has become partners with the Drug Source Co., a distributor of generic drugs based in Westchester, Illinois.

The American company helped Hisun gain regulatory approval to make ingredients for a variety of drugs. The drugs sold in the United States are Hisun's most profitable product lines and are its fastest-growing source of revenue.

Drug Source did not answer phone and e-mail messages seeking comment about its relations with the company.

Hisun has undergone seven inspections by the Food and Drug Administration in recent years. They were intended to ensure that the company meets U.S. standards for product safety. Hisun passed the inspections, and it is now certified to sell ingredients for at least eight medicines to the United States, all distributed by Drug Source.

Eli Lilly & Co. has also joined with Hisun to produce Lilly's drug capreomycin. Similar alliances have helped Hisun crack the European market for pravastatin sodium.

A spokesman for Eli Lilly said the company had no knowledge of environmental or safety problems at Hisun. The Food and Drug Administration declined to answer questions about its inspections of Hisun or its certification process.

Taizhou's main industrial area, Yantou, where the Jiaojiang River meets the East China Sea, was historically popular among fishermen, who used the river as a sheltered harbor.

In the mid-1980s, the local government renamed the area the Yantou Pharmaceutical Chemical Industry Zone, with state-owned Hisun as the anchor tenant.

Hisun initially focused on the Chinese market. But over the past several years, it has ventured into foreign markets with the help of its powerful North American allies.

Powered by exports, Hisun's sales are on track to hit \$150 million this year, and its campus of white-and-

blue-tiled factories and offices has expanded to cover dozens of hectares along the waterfront.

Internal reports by local and national environmental investigators have found that each year, Hisun and other nearby companies release 3.6 million tons of water laden with organic and inorganic compounds that receive little or no processing.

Yantou's shoreline is edged with sludge. Inland, the air is sulfurous. Fishermen say river water and seawater causes their hands and legs to become ulcerated.

The effect on some of Hisun's employees has also been severe.

Until recently Cao Hongshai was a Hisun assembly line worker who made a deworming medicine.

Cao said she used toluene, a toxic solvent, to produce the active ingredient in the drug. But she wore only a blue cotton uniform and worked in a room that had no special ventilation.



Cao says she has not suffered health problems except for irregular periods. But two years ago she gave birth to a girl who had stubs where eight of her fingers should have been.

Cao and her husband, Lin Jianyong, sued Hisun for damages. A report submitted to the court by the government-run Medical Information Institute in Zhejiang Province found a "clear correlation" between the child's defects and the chemicals used at Hisun.

Cao and Lin named their daughter after Hisun. Lin said they selected the name so that their daughter will always know that her deformity was the company's fault.

Local government officials have recently taken steps to clean up Yantou. Authorities opened a wastewater treat-

ment facility just a short walk from Hisun's campus, and local companies are now required to channel their runoff there and pay for it to be processed.

Beijing has also expressed alarm. Prime Minister Wen Jiabao has ordered environmental and safety agencies to investigate, according to people who say they were told of the prime minister's intervention.

But by the accounts of Hisun employees and some local officials, the company became adept at fending off such inquiries.

On Aug. 14, word spread at Hisun that a central government inspection team was to arrive from Beijing. Shen, the migrant worker who handled construction jobs for Hisun, noticed people bustling about the factory that day. But it was not until night that he and Feng were recruited to help the company prepare for inspections.

The boss explained that Hisun had a problem that needed immediate attention. Feng, who led his own construction brigade, was told to pick a colleague and bring flashlights, a sledgehammer and a drill. Feng roused Shen, his brother-in-law.

Shen said the boss told them what to do. They were to knock down barricades that had been built inside Hisun's sewage system to redirect the flow of liquid waste. He did not explain why.

It seems quite likely, some other employees and local residents said, that the company had diverted wastewater to avoid paying fees to have it processed, and that the pending inspections had prompted the company to restore the flow.

Feng stripped off his shirt and climbed down a manhole. He had just begun working below when he cried out and reached for help. Shen grabbed his bare arm and pulled with all his strength. He tugged so hard that he bit off the tip of his tongue. The shot of pain in his mouth is his last memory that night.

When Shen regained consciousness two days later, he asked for Feng. He was told his brother-in-law was dead.

So were Tang and a security guard involved in a rescue attempt.

A local government official, Wang, who declined to provide his full name or have his title used, said a deputy general manager of Hisun and a lower-level official in charge of the drainage system were under investigation.

Hisun itself was fined the equivalent of \$5,400, this official said. Relatives of Feng said Hisun had paid them \$20,500 compensation.

The local official said Bai Hua, Hisun's chief executive, was also assessed a personal fine. But neither Bai nor his company has said anything publicly about the case.

The New York Times