

**Press Release
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For immediate release

EU FOOD SUPPLEMENTS DEBATE MOVES TO OXFORD UNIVERSITY

One of Oxford University's largest student societies, the Oxford University European Affairs Society, hosted a debate last night on the controversial EU Food Supplements Directive. Presenting at the Society's evening meeting was author and former journalist Bert Schwitters, also CEO of the Netherlands-based International Nutrition Company. Lively and stimulating debate followed Mr Schwitters' inspiring speech, which detailed how the Precautionary Principle had been misapplied to health policy and food supplement law in Europe.

Schwitters demonstrated how the precautionary principle was born out of the Rio Declaration in 1992, when thousands of policy-makers and activities convened to determine ways of limiting carbon dioxide emissions and other aspects of human activity which so seriously endanger the earth's environment. This Declaration, aiming to protect whales, tropical rainforests and polar bears, states that "lack of full scientific certainty shall not be used as a reason to postpone measures."

When the European Food Safety Authority was established in 2002 under an EU Regulation, the Rio Declaration, intended for the protection of the environment, was transposed to health policy in the European Union. Its applicability to EU food supplement law was firmly clarified by the European Court of Justice, in its ruling on the Alliance for Natural Health's case challenging EU-wide bans on food supplements.

Schwitters went on to explain how the precautionary principle, combined with the EU principle of high level of public health protection could wreak havoc with a third key EU principle of law, the principle of free movement of goods.

Schwitters added, "The precautionary principle serves not only as a tool for trade restriction. It also helps European regulators who are faced with the problem of approximating the many different laws of the Member States. When applied in an existing theoretically "common" market as an overriding regulatory tool in the process of ironing out the differences between laws and regulations of Member States, the precautionary principle makes the ironing redundant by first exhausting, without recourse, the fundamental right to market participation. As long as the "information" is embedded in and surrounded by "scientific uncertainty," the precautionary principle can hit and remain in force anywhere in the form of "provisional risk management measures."

It is expected that unless challenge in the Courts, the precautionary principle, misapplied to EU public health policy, may provide one of the greatest obstacles to freedom of choice in healthcare.

ENDS.

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EDITOR'S NOTES

[The complete speech given by Bert Schwitters at the Oxford University European Affairs Society meeting is provided as an addendum to this release]

International Nutrition Company

The International Nutrition Company, INC, is the Netherlands-based, worldwide source of Dr Jack Masquelier's original patented Oligomeric ProanthoCyanidins (OPCs). For further information, see www.inc-opc.com

Alliance for Natural Health

The Alliance for Natural Health (ANH) is a Europe-wide non-profit alliance of consumers, doctors, complementary health practitioners, and innovative industry manufacturers and suppliers who have an interest in food supplements and natural health. More information, including details of the ANH's support base, will be found at www.anhcampaign.org.

Good science and good law underpin all of the ANH's work, and the scientific reports produced by the ANH are endorsed by many of the world's leading doctors and scientists working in the field of nutrition.

Speech

Oxford University European Affairs Society

Oxford, 11 May 2006

by
Bert Schwitters

The Precautionary Principle - Something is Rotten in the Affairs of Europe

Mr. Chairman, Ladies and Gentlemen, members of the European Affairs Society, it is an honour to speak to you about European affairs in one of Europe's oldest and most renowned universities. This is the place where Western science first materialized and came to great bloom.

Even though I am not a scientist by university training, I did acquaint myself with the craft of fact finding and research. In my professional life, I learned those investigative skills as a journalist who worked for television, radio and the printed media. Subsequently, I then applied in business what I had learned in journalism. Ever since the early 1980s, when I became involved in the food supplements business, I kept on looking behind backdrops and often found myself in the School of Hard Knocks. By the way, that's where I received my degrees.

But whatever subject or issue I was involved with, writing about it was what always gave me the greatest joy and satisfaction. And, now that I'm here in Oxford, you may wish to know that I'm also addicted to rowing. So, let me express my somewhat belated congratulations for your victory in this year's Boat Race.

For starters, I did some investigative work and found that your European Affairs Society's events aim at providing a balance between "socio-political and cultural events". I was particularly delighted when I discovered that over here "cultural" not only means European film nights and various garden parties, but also drinks parties and food and drink tastings. You will need a drink when you've finished listening to what I'm going to tell you. For those of you who've come to Oxford because they feel that science should mean something to society, I cannot bring you good news from the European socio-political arena.

I am involved in that arena because, first of all, I'm Dutch and that makes me a citizen of the European Union. Secondly, I own a company that is trying to save its products from drowning in the Tsunami of rules and regulations designed by the thousands of bureaucrats who occupy the floors of the European high rises in Brussels. I can tell you that there's no better way of finding out how Europe works than when you suddenly find your business, your products, your employees and in the last instance yourself, at the risk of being deprived of certain rights and privileges you had under national laws. Thirdly, and this is something of particular interest in a University setting, I think that science, innovation, research, discoveries and pioneering are always at the root of progress, health and wealth. So, it disturbs me when I see that the European government has banned science from their decision making process.

Doing away with science would make what you practice here in these historic surroundings redundant in the context of European Affairs. The idea that science should

no longer influence decisions makers, was not launched in Europe, but in Rio de Janeiro, where, in 1992, thousands of policy-makers and activists from all over the world drew up the following Declaration:

I quote: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

As you know, when States take measures, it is always in the form of enforceable laws, rules and regulations. In the European Union, such enforceable measures are gently called "Directives". By the way, the Rio Declaration became known as the Precautionary Principle. Eventually, it gave rise to the Kyoto Treaty. In Europe it produced disguised trade restrictions in fields other than CO2 emission. So, the influence of these few words is profound and far reaching.

How can this honorable principle possibly have detrimental side effects ? After all, protecting the whales, the tropic jungles and the polar bears from threats of serious damage is beyond reproach and beyond discussion. Contrary to suggesting that we should fish whales and shoot polar bears, I do think that the Precautionary Principle pollutes not only science, but many other aspects of our society, more especially the judicial system and public health. Eventually, I even think that the Rio Declaration will do more harm than good to the environment.

Let me demonstrate my point by drawing your attention to the fundamental flaw in the Rio Declaration, which states that "lack of full scientific certainty shall not be used as a reason to postpone measures." This means that science and universities where science is practised were effectively removed as a hindrance rather than a tool to formulate enforceable and provisional measures. Science appeared to be in the way of the thousands who flew to Rio to save our planet. In the Halls of Academia, the Rio Declaration should have rung a bell.

Since the Rio conference, the Precautionary Principle was enthusiastically and quickly adopted by those Europeans who are in a position to propose, take, execute, confirm and enforce measures, that is, by most politicians, by regulators, bureaucrats and judges. Without a doubt, many of those measure-takers are scientists by training, but, looking at the speed and profoundness at which the Precautionary Principle permeated the world of European regulations, the scientists among them didn't seem to mind that since the Rio declaration, science may no longer be used as part of the equation used to formulate measures. Perhaps it came as a relief to some of them.

As you all know, the European Union is not run by a democratically elected government. Instead, we have installed power in a handpicked Council which is assisted by thousands of equally unelected and equally handpicked bureaucrats. You can imagine why the precautionary principle fell on fertile soil in Brussels. Soon, the principle was given a predominant place in the official Treaty that forms the foundation of the European Community. The precautionary principle dovetails wonderfully with another principle that is written in the high banners of the European Union. It's the principle named: "high level of protection". Combining threats of serious or irreversible damage with a high level of protection, the principles of precaution and protection become a unique and practically invincible couple.

Reading the text of the Treaty, one might conclude that the European Commission intended to apply the precautionary principle especially to formulate policies that aimed at a high level of protection of the environment. Such in accordance with what the Rio conference had in mind. Yet, in December of the year 2000, the European Council broadened the number of fields to which it decided to apply the precautionary principle.

During the Council Meeting that was held in Nice, the leaders of Europe decided that, I quote from the text of the Council Resolution: "... this principle is also applicable to human health, as well as to animal health and plant health sectors."

Keeping in mind the Rio definition of the precautionary principle, this means that the European Council officially declared that, when it comes to taking measures, science doesn't matter in the fields of human, animal and plant health. Some of you may feel that I'm exaggerating. Some of you may find it unbelievable that the European Union would officially reject science as the key-element in the process of taking enforceable and provisional measures. Bear with me for another 20 minutes and you'll see that I'm not hallucinating.

While peacefully eating their "salade niçoise" at the Côte d'Azur, the European Council injected the precautionary principle deep into the bloodstream that keeps the regulators in Brussels alive. Our respectable and honorable European leaders figured that it might be worthwhile, I quote from the official Resolution, "to examine ... whether it is necessary and possible formally to consolidate the precautionary principle, in accordance with the case law of the Court of Justice of the European Communities, also in other Treaty provisions specifically concerning health and consumer protection." The seed that was carefully planted in Rio de Janeiro to save the planet, irrespective of scientific research, suddenly came to full bloom as an unlimited regulatory instrument in the Bureaucracy called European Union.

Setting the stage for the remainder of my speech, let me highlight another guiding principle that plays a role in the European Union, and that is the free movement of persons and goods. Free movement meaning that any product that is being legitimately sold in one of the Member States should not suffer from any national restrictions and that it should be available to consumers throughout the Community. Ideally, the EC was designed to be a level playing field that indiscriminately provides free movement and market entrance to all players at perfectly equal conditions. The Boat Race could serve as a model for this. Two teams enter the race on perfectly equal conditions.

This is why, heeding this principle of free movement, the European Council expressly stated in its Nice Resolution that, I quote, "the precautionary principle must not be used in order to introduce disguised trade restrictions." "Trade restrictions?", you may ask, how could the principle designed to save the planet be used as a trade restriction in disguise?

Well, let me give you an example. Suppose that here in the UK, health food stores would legitimately sell legitimate food supplements. Compact forms of vitamins, minerals and other essential nutrients to supplement your diet with. Products that have been tested by their suppliers and by the relevant British food safety authorities. Products that, under the principle of the free movement of goods, should be available to all citizens of the European Union, no matter where they live. Suppose that you'd want to deprive these legitimate British food supplement of their entitlement to free movement throughout the European Union, because you wouldn't wish that they became available to consumers outside Albion. It means you'd have to somehow rig the principle of free movement.

Using the Precautionary Principle, you could then simply allege that, even though the British authorities consider these food supplements as safe and perhaps even beneficial, there's no "scientific certainty" that they will never do any harm to anybody. Maybe, who knows, there's a little old lady who reported stomach pains after having taken vitamin C. It doesn't matter, you simply dream up something and without evaluating any scientific research, you could simply suggest that there's a possibility of

risk, and demand that until it shall be proven that no risk exists, the British products must be deprived of their fundamental right to free movement in the European Union.

If you wanted to protect your, let's say, German market, this is how you could use the precautionary principle as a disguised restriction to trade. Within the European setting, this would of course mean that eventually even in the UK, those legitimately sold food supplements would have to be removed from the shelves, with the poor British citizens who depend on these products for their health as casualties in a trade restrictions war.

However, reading the December 2000 Council Resolution, preventing the use of the precautionary principle as a disguised weapon in trade wars amongst Member States is precisely what the honorable members of the European Council and the Heads of State had in mind when they solemnly etched in stone that the precautionary principle should not be used as a disguised trade restriction.

Let's recapitulate here for a moment. To raise the precautionary principle as a trade restriction in disguise, the only thing you need to do is suggest that there's a risk, raise your right hand and make a solemn statement that you aim at a high level of protection of human health, demand scientific proof of no harm, and then, while consumers, industry, lobbyists and scientists come into action, issue a provisional and enforceable measure that works as a disguised restriction to trade.

The crux of the matter is that the precautionary principle is a regulatory tool that allows States and authorities to introduce provisional measures that are enforceable without having to weigh, assess or even care about scientific data. Scientific knowledge no longer matters. Suggesting risk and threats is sufficient. And, there is no recourse and possibly antidotal counter-argument because supplying scientific proof of no risk is an impossibility.

Interceding on behalf of consumers, animals, plants or the environment at large, the precautionalist can drastically intervene in a market or another segment of society, before scientific data can and may be weighed. The true precautionalist doesn't care about weighing and assessing scientific data. He cares about something that he deems so important that measures even draconian ones must and shall be taken, irrespective of what scientists have to say about it. The true precautionalist doesn't even care about proper scientific risk assessment. In fact, the fact that something is the subject of risk assessment forms good ground to apply the precautionary principle. That's why I call the precautionary principle "ante-scientific". "Ante" as in "anterior". It is not anti-scientific per se, it merely takes science out of the equation that leads to enforceable provisional measures.

As a side-step, speaking of risk assessment, most people think that risk management should be based on the outcome of the risk assessment. However, when you allow risk managers to use the precautionary principle, which is common practice in the European Union, you make risk assessment redundant in the regulatory process because you intervene with provisional measures before you know the outcome of the risk assessment.

Now, let's return to the UK and to those safe and legitimately sold British food supplements. In 2002, the European Commission issued a Directive in which it professed to aim at a broad stroke "Schengen" type removal of the archaic national frontiers that have always impeded the free movement of food supplements in Europe, especially from the Member States that traditionally permitted liberal amounts of essential nutrients in such products, to European states that applied more to very restrictive regimes. It all sounded well, but in its nitty-gritty, the Directive took a highly restrictive stance, and thus violated the principle of free movement of goods. In fact, the Directive worked as a ban on many legitimate British and Dutch food supplements.

That's why the Alliance for Natural Health challenged the Directive all the way up to the European Court of Justice.

It may not come as a surprise to the members of the European Affairs Society, that before the European Court makes a decision, it has the case evaluated by an Advocate General. An Advocate General at the European Court of Justice is not an inexperienced feather-weight legal amateur. In the case that was brought by the Alliance for Natural Health to test the validity of the Food Supplements Directive, my fellow countryman, Advocate General Ad Geelhoed, prepared the Opinion for the Court. In an extremely well detailed Opinion, Geelhoed exposed the Food Supplements Directive as an ill-wrought piece that causes enormous prejudice to trade and consumers. Assessing the banning of legitimate food supplements, Geelhoed wrote, and I quote: "without calling in question the substantive assessment made by the Community legislature, I must conclude that it has seriously failed in its duty to design such a far-reaching measure with all due care." The "legislative technique applied here," so wrote Geelhoed, "does not merit such a title."

Geelhoed's evaluation of the procedure offered by the authors of the Directive to food supplement manufacturers who might want to undertake saving a banned nutrient from certain death, was equally negative. I quote Geelhoed: "In so far as this procedure may exist and in so far as it may deserve this title," it has "the transparency of a black box: no provision is made for parties to be heard, no time-limits apply in respect of decision-making; nor, indeed, is there any certainty that a final decision will be taken."

I suspect that Leendert Geelhoed still lives in pre-Precautionary Principle times, when interested parties such as, in this case, responsible companies making, distributing and selling legitimate food supplements, still deserved some basic form of protection against indiscriminate bureaucratic bias and arbitrariness. "In order to ensure," so admonishes Geelhoed, "that these interests are taken into account in the decision-making process in a manner which is open to judicial scrutiny, the basic legislative act ought for that purpose to provide for the minimal guarantee of an adequate procedure." Meaning, in my words, a procedure that companies should be permitted to follow prior to their products being removed from the market.

Geelhoed found that the procedure proposed in the Directive "... lacks essential guarantees for the protection of the interests of private applicants." Respecting good old Pre-Precautionary-Principles, Geelhoed continues: "the Community legislature in drafting a legislative act may at least be expected to act with such care as to make express provision for minimum conditions of prudent decision-making in that legislative act. The fact that these conditions were not included in Directive 2002/46 is in itself sufficient to conclude that the Community legislature has failed in this respect. The Directive does not comply with essential requirements of legal protection, of legal certainty and of sound administration, which are basic principles of Community law. Thus, lacking appropriate and transparent procedures for its application, the Directive infringes the principle of proportionality. It is, therefore, invalid."

Unfortunately for Geelhoed and the Alliance for Natural Health, the Advocate General bit the dust. When he and the Alliance got up and wiped the dirt from their faces, they saw what had brought them down. As you've already guessed, indeed, it was the precautionary principle, which is not even embedded in the Food Supplements Directive itself. Take a moment to let this sink in and absorb the full meaning of this. All that Geelhoed had carefully and quite reasonably explained was swept under the carpet by the precautionary broom.

That broom came out of the closet called Regulation No 178/2002 that installed the European Food Safety Authority, better known under its abbreviated name as EFSA. As

does the Food Supplements Directive, the EFSA Regulation solemnly professes to honour and strive for the principle of free movement of foods and food supplements. However, the EFSA Regulation also makes reference to the precautionary principle.

Here's the deal presented in Article 7. I quote: "In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment."

In everyday language, this means that under the flag of a high level of health protection, measures may be adopted without weighing or evaluating scientific data. The precautionary principle is the club that may hit when "information" becomes "available". Must that information be specific and must it relate to a visible, factual, verifiable event? The EFSA Regulation doesn't tell. All that is required is that the information alludes to, suggests, perceives or simply evokes a "possibility of harmful effects."

"What's that?", you may ask. "Possible" meaning "capable of happening," the word "possibility" opens up a field as wide as this universe. Must the source of the "information" be known? Is it mere gossip, disinformation or propaganda? Is it necessary that the supplier of the information declares and explains how he or she obtained or observed the information? The EFSA Regulation doesn't tell and there is no qualification of "information" in the Regulation. As long as the "information" is embedded in and surrounded by "scientific uncertainty," the precautionary principle can hit and remain in force anywhere in the form of "provisional risk management measures."

The European Court of Justice clarified in its ruling that the precautionary principle, as laid down in article 7 of the "EFSA" Regulation, is the fundamental regulatory tool that allowed the Commission to place micronutrients under an a priori suspicion of lack of safety, guilty until proven innocent. Compared to most medicines, micronutrients are harmless and safe, and their marketing in the form of food supplements poses no "clear and present danger" to public health. Yet, the precautionary principle was applied to effectuate the removal of legitimately sold food supplements in the more liberal Member States. This regulatory practice, whereby an instrument of last resort, the precautionary principle, is used in situations that do not objectively call for such a regulatory instrument, raises the question whether the precautionary principle wasn't used more to overcome the difficulties that are inherent to approximating the relevant laws of the Member States, than to prevent an imminent danger to public health.

The precautionary principle serves not only as a tool for trade restriction. It also helps European regulators who are faced with the problem of approximating the many different laws of the Member States. When applied in an existing theoretically "common" market as an overriding regulatory tool in the process of ironing out the differences between laws and regulations of Member States, the precautionary principle makes the ironing redundant by first exhausting, without recourse, the fundamental right to market participation. Applied in the European Common Food Supplement Market, this is how market participants were effectively deprived of their fundamental right to freely move goods (food supplements) in one Member State and from that state to another Member State. Only a handful of market participants seems to realize the workings of the precautionary principle.

Without too much intellectual training, the case of the Food Supplements Directive can be understood as an unequivocal demonstration that the European Council is prepared to violate its written promise that the precautionary principle would not be used as a disguised restriction of trade. In other words, the precautionary principle squarely

conflicts with several other principles, especially with that of the free movement of goods.

What I've been trying to explain to you here during this wonderful evening, is that if you're interested in European Affairs, you will somehow encounter the precautionary principle as the somewhat barbaric regulatory "technique" that can unfairly upset existing markets, that can overrule and set aside prudent and appropriate risk assessment, and that can block innovative scientific and technological developments.

That's why my company sponsored an independent scientific project to develop a straightforward, rational, transparent, and scientifically coherent benchmark methodology to regulate food supplements cost-effectively within a European, or even a global, level-playing field in which assessment and management are explicitly linked. The study also addresses the problems arising from the indiscriminate use of the precautionary principle and the way the principle does away with and perverts science.

As far as the European 'precautionists' are concerned, you may all go home ... and stay home. There's no more need for your science contributions to their European Affairs.

As far as I'm concerned, let's share the rest of this evening in good companionship and in an atmosphere that will allow the free movement of ideas and thoughts.

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