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~ A Lawyer's Perspective ~

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MANAGING RISKS

~ With Precaution ~

A Lawyer's Perspective

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AREAS COVERED IN THIS PRESENTATION

- 1. Development of the Precautionary Principle ('PP') in the EU.**
- 2. Precaution on the International Stage.**
- 3. Overview & Future Developments.**

DEVELOPMENT OF 'PP' IN THE EU

A Decade of Precaution

EC Treaty (1993)



Early Case Law (1993-2000)



Commission Communication (2000)



Recent Case Law (2000-2003)

PP appears only once in the EC Treaty, Art. 174(2), and is not defined:

*‘Community **policy on the environment** shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It **shall be based on the precautionary principle** and on the principles that **preventive action** should be taken, that environmental damage should as a priority be rectified at source and that the **polluter should pay.**’*

Early Case Law: BSE Cases

Cases* mark a watershed - judgments where the approach was applied and upheld (though *without explicit mention of PP*).

The BSE Decision, *temporarily* banning export of bovine animals, meat and derived products from UK to other MSs, acknowledged serious concern among consumers.

**C-180/96 & C-157/96*

Highlights of ECJ Reasoning in the BSE cases:

1. Decision taken when ‘great uncertainty’ on risks.
2. EU institutions may act to protect ‘human health’.
3. “Emergency” & Temporary measure to be ‘subjected to detailed scientific study and ... review ...’.

Commission Communication

(2.2.2000)

- ☀ **Confirmed wide scope of PP - where potentially dangerous effects on the environment, human, animal or plant health;**
- ☀ **outlined Commission's approach to using PP;**
- ☀ **established Commission guidelines for applying PP;**
- ☀ **contributed to a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully and input to the ongoing debate at EU and International level; and**
- ☀ **warned against 'unwarranted recourse to' PP as disguised protectionism.**

Communication: How to decide *if* PP should be applied:

- ✿ **‘Judging what is an "acceptable" level of risk for society is an eminently political responsibility.’**
- ✿ **‘Should start with a scientific evaluation, as complete as possible’, identifying level of uncertainty at each stage.**
- ✿ **Transparent decision-making procedure.**
- ✿ **Involve ‘all interested parties’ ...as early as possible and to the extent reasonably possible.’**

Communication: *If decide to apply PP:*

Binding legal measures in response will not always be appropriate. All action should be:

- ✿ proportional;
- ✿ non-discriminatory;
- ✿ consistent with similar measures already taken;
- ✿ based on examination of potential benefits and costs of action or lack of action;
- ✿ subject to review; and
- ✿ capable of assigning responsibility for producing the scientific evidence.

Recent Case Law: GMO Case

*Greenpeace France case** - ECJ rejected the argument that PP could be applied as a free-standing “trump card” where PP already forms part of the regulatory regime for placing a product on the market in the EU.

This means that, *at least*, in all cases where an EU harmonised risk assessment procedure applies, neither Commissions or MSs can apply PP in conflict with underlying secondary legislation.

*C-6/99

Recent Case Law: Feedstuff Additive Cases

Cases* Pfizer / Alpharma consolidated legal rules and hurdles for use of PP. Some key points:

- ☀ Scientific uncertainty not a necessary bar to taking preventive measure.
- ☀ May not base decisions on a 'zero-risk' requirement.
- ☀ A 'preventive measure cannot properly be based on a purely hypothetical approach to the risk'.
- ☀ Must be 'adequately backed up by the scientific data available at the time when the measure was taken' even if not 'fully demonstrated'.

**T-13/99 & T-70/99*

 **Two complementary components of risk assessment which ‘must not be confused’:**

a) Conducting a scientific assessment of the risks

- **Does not have to be conclusive BUT ...**
- **Must enable the competent public authority to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society and which measures appear to it to be appropriate and necessary to prevent the risk from materializing.**

b) Ascertaining what level of risk is deemed unacceptable

- political choice turning on the facts of each case, taking into account factors including:**
- severity of the impact on human health were the risk to occur;**
- extent of possible adverse effects;**
- persistency or reversibility of those effects;**
- possibility of delayed effects; and**
- even the more or less concrete perception of the risk based on available scientific knowledge.**

Scientific (expert) Committees

Although consulted under various pieces of legislation by the Commission, the opinions they deliver are NOT binding.

Community institution that disregards (wholly/partly) an opinion, ‘must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding’ it.

The statement of reasons must be of a scientific level at least commensurate with that of the opinion not followed.

Recent Case Law: Medicinal Products Cases

This time last year, CFI declared* PP as:

‘... a general principle of Community law requiring the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests. Since the Community institutions are responsible, in all their spheres of activity, for the protection of public health, safety and the environment, the precautionary principle can be regarded as an autonomous principle stemming from the abovementioned Treaty provisions.’

Repeated this year by CFI but not yet confirmed by ECJ

**Joined cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00;*

repeated by CFI in case T-147/00 16

'PP' ON THE INTERNATIONAL STAGE

International Environmental Agreements

“Precaution” is cited in many texts but no clear definition is commonly agreed.

WTO Sanitary and Phytosanitary Agreement

Permits Members to ‘determine the level of protection which they deem appropriate provided that action is taken ‘only to the extent necessary ... based on scientific principles and ... not maintained without sufficient scientific evidence’.

WTO Sanitary and Phytosanitary Agreement (cont'd)

‘...where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members ... Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.’

OVERVIEW & FUTURE DEVELOPMENTS

- ✿ The past decade has seen the evolution, in the EU, of PP from one of many principles underlying environmental policy to one applied in fields including, human, animal or plant health (see e.g. Regulation 178/2002 on general principles of food law Articles 6(3) and 7).
- ✿ It may even now - perhaps - be considered a general principle of Community law. Confirmation of CFI's view is required.
- ✿ The PP's scope has been somewhat clarified by recent case law.
- ✿ Community institutions can act in situations of scientific uncertainty. **HOWEVER** the precise boundaries on them and obligations placed upon decision makers still require clarification.

LESSONS LEARNT & FUTURE ACTION

- ✿ **The European Court maintains its traditional deference. It refuses to step into the shoes of decision-makers. This leaves a wide – probably too wide - discretionary power with the Community institutions - which is often unchecked because of the restrictive rules of standing before the European Court.**
- ✿ **A clear definition of the PP is unlikely to come out of the IGC.**

LESSONS LEARNT & FUTURE ACTION

- ✿ **At the International level, discussions around the theme of precaution might be touched on in part of the current trade round (though WTO Members could not agree enough to put any explicit reference in the Doha Declaration).**

LESSONS LEARNT & FUTURE ACTION

AT THIS POINT, GREATER LEGAL CLARITY IS REQUIRED.

This could happen in one of three ways:

- 1. Treaty amendments (feasibility);**
- 2. A new Communication (possible);**
- 3. Further legal challenges (not desirable).**

Unless 1 or 2 happens, 3 will certainly follow!