Precaution and Labeling

What Do They Mean for International Regulation?

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What do we mean when we talk about Precaution?

- No one denies Precaution is good.
- Turning "Precaution" into meaningful regulatory guidance is difficult.
- Most regulation already incorporates Precaution in some way (pre-market evaluation).
- Major debate is over Precautionary Principle and/or Precautionary Approach – what they mean and how (if) to implement them.

What is the Precautionary Principle?

"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."

(Rio Declaration, 1992)

PP "seeks to impose early preventive measures to ward off even those risks for which we have little or no basis on which to predict the future probability of harm."

(J. Wiener, 2001)

How Do PP, Ordinary Precaution Differ?

- Complete certainty is impossible, but traditional precautionary measures try to identify hazards and then manage identifiable risk.
- PP advocates believe this approach under-protects public and environment – weak signals.
- PP intended to be open-ended, proactive, and maximally responsive to public input.
- Lack of definition or uniformity is a "designed-in" feature of the Precautionary Principle.

Drawbacks of PP

- No agreement on when, how, and how long to apply PP, or to which products.
- Intended to be public-driven rather than expert-driven – subject to groundless fears, and often out of proportion to genuine risk.
- Ignores risks that arise from forgoing certain products or technologies.
- Application seems to be driven primarily by political pressure, with little or no relationship to actual consumer or environmental protection.

What Does PP Have to Do With Labeling?

Similar trend in consumer labeling policies:

- Ad hoc, under pretense of making labeling more responsive to the public.
- Focuses attention only on "politically correct" environmental or consumer risks.
- Belief that labeling indicates risk causes some consumers to forgo beneficial products.
- Lack of established decision rule means labeling decisions tend to be arbitrary.
- Same arbitrariness makes process subject to politicization.

Beef Hormone Case

- EU claimed PP justified ban on US and Canadian beef from cattle treated with growth promoters – including naturally derived supplemental hormones.
- No risk identified by EU when hormones are used with good animal husbandry practices.
- Endogenous hormone levels often higher in un-castrated/un-treated animals than treated ones.
- EU did not ban growth promoters in pork industry, where many European producers are globally competitive.

Corn Flakes

Norway invoked PP in prohibiting sale of Kellogg's Corn Flakes fortified with vitamins because "the fortification in question might be a health hazard when eaten in ***uncontrollable and unforeseen*** amounts" (emphasis added).

--*EFTA Surveillance Authority v. Norway*, 2001. Case E-3/00, 2 C.M.L.R. 47. European Free Trade Association Court, Luxembourg.

Fruit Juice

Denmark used PP to prohibit sale of Ocean Spray Cranberry Drink on the grounds that added vitamin C could be harmful to some consumers.

--*Commission v. Denmark*, 2003. Case C-192/01, E.C.R. 0 (Advocate General).

Caffeinated Drinks

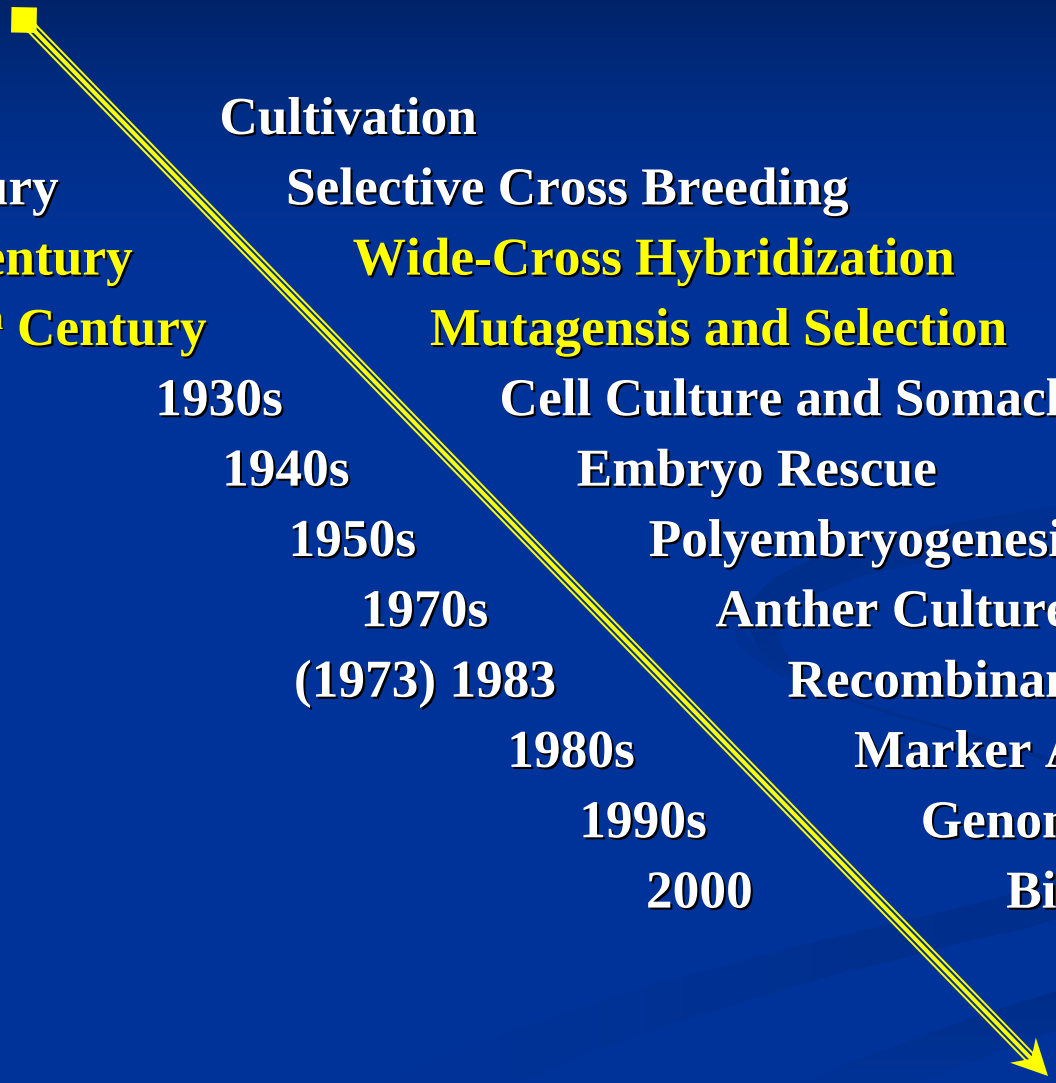
France used PP to prohibit sale of Red Bull caffeinated energy drink on the basis that consumers – particularly pregnant women – would ingest too much caffeine.

--*Commission v. France*, 2004. Case C-24/00, ECR 0, ¶ 67 (ECJ).

Bioengineered Food Labeling

- Advocates who favor labeling bioengineered foods claim they could pose unknown hazards and that consumers have a right to know that and make a choice.
- Less is usually known about the chemical and genetic composition, as well as environmental behavior, of conventionally-produced crop plants.

Crop Breeding Technology Timeline



Wide Cross Breeding Introduces New Traits (New Genes) From Wild Species

Lycopersicon esculentum (VFNT)

Lycopersicon peruvianum

Common Plant Toxins and Antinutrients

Toxin Family	*Occurrence in Food Plants*	*Effect on Humans and Animals*
Cyanogenic glycosides	Sweet potatoes, Stone fruits, Lima beans	Gastrointestinal inflammation; Inhibition of cellular respiration
Glulcosinolates	Canola, Mustard, Radish, Cabbage, Peanut, Soybean, Onion	Goiter; Impaired metabolism; Reduced iodine uptake; Decreased protein digestion
Glycoalkaloids	Potato, Tomato	Depressed central nervous system; Kidney inflammation; Carcinogenic; Birth defects; Reduced iron uptake
Gossypol	Cottonseed	Reduced iron uptake; Spermicidal; Carcinogenic
Lectins	Most cereals, Soybeans, Other beans, Potatoes	Intestinal inflammation; Decreased nutrient uptake/absorption
Oxalate	Spinach, Rhubarb, Tomato	Reduces solubility of calcium, iron, and zinc
Phenols	Most fruits and vegetables, Cereals, Soybean, Potato, Tea, Coffee	Destroys thiamine; Raises cholesterol; Estrogen-mimicking
Coumarins	Celery, Parsley, Parsnips, Figs	Light-activated carcinogens; Skin irritation

Mutation Breeding

Gamma Field: Co-60 @ 100m Radius

Institute of Radiation Breeding – Ibaraki-ken, Japan

More Than 2,250 Mutant Varieties

Beyond™ herbicide tolerant –

Clearfield Wheat

Clearfield Canola

Qualities Argued to Necessitate Precautionary Regulation or Labeling

	Toxins or Allergens	Positional Effects	Altered Nutrient Content	Invasive-ness or Weediness	Non-Target Impacts
rDNA-modified	✓	✓	✓	✓	✓
Wide Crosses	✓	✓	✓	✓	✓
Mutant Varieties	✓	✓	✓	✓	✓

Do Labels Inform Consumers?

- Labeling only bioengineered foods means that most of the supposed reason for labeling is missed.
- If label says "Genetically Modified," then nature of the risk is not transmitted to consumers – half or more of consumers self identify as knowing little or nothing about biotechnology.

Right to Know What?

- Labeling advocates claim consumers:
  - Want to know how their foods were created, and
  - Have a "right to know" what's in their food.
- If these claims are valid, then why shouldn't labeling indicate:
  - The way ALL foods were created?
  - Don't consumers have an equal right to that information?
- Makes more sense to regulate/label characteristics than to regulate/label process.

Sloppy Labeling Definitions

- Oregon Ballot Measure 27 would have defined many non-bioengineered products as "genetically engineered."
- Any food or beverage that is "grown, manufactured, processed or otherwise produced or altered with techniques that **change the molecular or cell biology** of an organism by means or **in a manner not possible under natural conditions or processes**" (emphasis added).
- Measure 27 "not limited to recombinant DNA techniques." Explicitly included "cell fusion, micro- and macro encapsulation, gene deletion and doubling, introducing a foreign gene, and changing the positions of genes."

Gerrymandered Definitions

EU Labeling and Traceability Rule:

- Products produced from bioengineered organisms must be labeled as "Genetically Modified."
- Products produced with bioengineered organisms not considered "Genetically Modified," and need not be labeled.
- European producers more competitive in "produced with" category.

Importance of Decision Rules

- Reliability and regularity of legal rules are essential for proper planning by businesses and individuals.
- Written, established laws clearly stating what is and what is not unlawful behavior is an essential bulwark of the freedoms protected by constitutional democracies.
- Lack of procedural rules grants unaccountable power to regulators and politicians – fairness demands that rules apply equally to similar cases.
- Science-based decision rules for regulatory policy and labeling are essential for promoting fairness, equity, and predictability.

Decision Rule for Labeling?

- Mandatory labeling should include all material changes in final consumer product:
  - Alteration of the chemical composition beyond normal variability, when change impacts health or nutritional aspects;
  - Alteration of organoleptic qualities, such as taste, color, odor, and feel; and/or
  - Alteration of storage or preparation characteristics typically associated with food product.
  - Other "material" alterations may qualify, but should be included only if they will be enforced for ALL products.
- Should not require disclosure of process or production methods – voluntary disclosure.

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