The European Novel Food Regulation:
Emerging trade barrier for non-traditional foods from developing countries

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IPGRI-What it is

• One of 15 Future Harvest centers, with a mandate to contribute to poverty alleviation through agricultural research

• Funded by donor and development agencies from developed and developing countries (CGIAR)

• IPGRI helps partners conserve and use genetic diversity (agriculture, forestry)
IPGRI - Outputs

- Collaborative research on plant genetic resources
- Conservation technologies, standards, policies
- Publications
- Tools (databases, software)
- Capacity building in national research organizations
- All outputs in the public domain!
Plant Diversity in South America

- 25,000 plant species (Peru)
- 1200 edible fruits (South America)
- 1400 medicinally used species (Peru)
- 70 crops domesticated (Andes)
Inventory of Native American Fruits

Approximately 1200 species, 285 genera, 66 families

- Arecaceae (105)
- Myrtaceae (102)
- Rosaceae (84)
- Cactaceae (75)
- Fabaceae (62)

- Sapotaceae (60)
- Passifloraceae (58)
- Melastomataceae (43)
- Annonaceae (41)
- Moraceae (34)

http://www.ciat.cgiar.org/ipgri/fruits_from_americas/frutales/fruits_from america.htm
Passion fruits (Passiflora spp.)
Camu camu
(Myrciaria dubia)

Up to
2000 mg Vit. C / 100 g
Cañihua grain (Chenopodium pallidicaule)
15-30 mg Fe / 100 g
Yacon (Smallanthus sonchifolius)
Yacon - Traditional uses

Huanuco farmer unearthing yacon

Rural women selling yacon, Puno
Geographical distribution of yacon

- 1983 from Ecuador to New Zealand
- 1985 Japan
- 2000 Taiwan
- 2003 Hainan
- 2003 Philippines
- 1991 Brazil
- 1998 S. Korea

1 propagule!
Yacon attribute discovery in Japan

- 2/3 of root dry matter is **oligo-fructose** (highest of all known plant sources)
- Anti-hyperglycemic principle in roots and leaves
- “Food value” and appreciation of texture
Yacon market presence, Lima 2003

Yacon products, Lima, August 2003

Yacon in Lima supermarket, November 2003
Maca roots (*Lepidium meyenii*)

Junín, 4300 m altitude
Natural Viagra Alternative - Maca Benefits -

- Improves erectile tissue response.
- Increases in men: semen volume and sperm count.
- Enhances fertility.
- Increases libido and sexual performance.
- Maca is found with no downside effects.

Maca 750 - Female Viagra
06/17/03
Female Viagra
In Scotland, a natural aphrodisiac being touted as the Female Viagra is

Pure Maca Products - Peruvian Ginseng
from The Amazon Company

Scientific name: Lepidium peruvianum

Contraindications and Warnings

- If you observe adverse reactions, discontinue use and consult your doctor.
- Store at cool dry temperature.
- Keep out of the reach of children.

How much should I take? Maca is a food. Its designation as an herb imparting specific health benefits is also true, but primarily maca is eaten as a food by very poor people living in a harsh environment where there is little else.

Maca 750 - Female Viagra
06/17/03
Female Viagra
In Scotland, a natural aphrodisiac being touted as the Female Viagra is

4 Mens Health

"From Peru to you..."

The South American country of Peru is home to numerous beneficial plants, including maca, a legendary sex-enhancing root passed down from the Inca. I'd heard about maca for years. It has been dubbed "Peruvian ginseng," even though it bears no relation to ginseng. But like ginseng, the plant is employed to increase strength, energy, stamina, libido and sexual function, a winning combination, according to some.

3 Macamor
Rejuvenating Tonic for Men & Women

The Greatest 'Feel Good' Product!

Helps renew your energy and restore your "passion" for life.

Macamor™ is a blend of two highly revered ancient natural ingredients. Maca and Elk Antler Velvet have been used traditionally for millennia to support healthy energy, metabolism, muscle strength, stamina, and hormone balance.
Maca products and marketing (Lima, November 2003)
## Scientific substantiation of folk medicine?

### Reported pharmacological effects of maca

<table>
<thead>
<tr>
<th>Effect</th>
<th>Species</th>
<th>Authors</th>
<th>Journal</th>
<th>Year</th>
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</thead>
<tbody>
<tr>
<td>Enhanced sexual function, aphrodisiac activity</td>
<td>Mice, rats</td>
<td>Zheng et al.</td>
<td>Urology</td>
<td>2000</td>
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<td>Increased testis weight and spermatogenesis</td>
<td>Male rats</td>
<td>Gonzales et al.</td>
<td>Asian J. Andrology</td>
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<td>Gonzales et al.</td>
<td>Asian J. Andrology</td>
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<td>Improved growth and survival of juvenile fish</td>
<td>Trout</td>
<td>Lee et al.</td>
<td>Manuscript</td>
<td>2003</td>
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In conclusion:

• Biodiversity - untapped resource for diet diversification
• Increasing demand from health, ethnic, organic, fair trade markets
• Potential for income generation of the poor
• Importance of research and development outside native range of traditional foods
• Recent crop transitions from subsistence to market presence
Current situation - EU Regulation 258/97

- Exporting firms’ complaints about legal uncertainty/confiscation of consignments
- 2 applications of exotic traditional foods declined since 1997
- More exotic traditional foods challenged
- Request to assist with food dossiers
Novel Food Regulation (258/97) appears to exempt traditional foods

Six food categories according to 258/97:

- Containing, or consisting of, GMOs
- Produced from, but not containing GMOs
- With modified molecular structure
- Derived from micro-organisms, fungi, algae
- Derived from new production processes
- Derived from plants & animals ...except those obtained by traditional propagating and breeding practices...
Stevia rebaudiana - refused

- Traditional sweetener in Paraguay, Brazil (30-45 times sweeter than sucrose)
- ODA agencies promoting production with a view on export markets
- Market admission refused in 2000
- Toxicity data deemed unsatisfactory to dispel food safety concerns; insufficient standardization of commercial product
Nangai nuts (Canarium spp.) - refused

- Almond-sized kernels, widely eaten and traded in East Asia and Pacific
- For French gourmet market, chocolate, confectionary
- Submitted compositional and toxicology data deemed incomplete; product allergenicity not investigated
Maca roots (Lepidium meyenii) - challenged

- Ancient root crop with documented food use since 16th century; closely related to a number of European Brassicaceae
- Acquiring ambiguous fame as Andean Viagra in the 1990s, and initially perceived in the EU as herbal medicine
- In some EU member states withdrawn from market through rapid alert system as falling under 258/97
- Widely differing practice of 258/97 in member states
- Eventually recognized as not falling under 258/97 because of presence in one country prior 1997
Noni (Morinda citrifolia) – one proprietary product admitted

• Long tradition as famine food and folk medicine of Polynesian people – alleged health promoting attributes

• Noni juice traded internationally and available on EU market after NFR came into force

• Commercialization suspended, after novel food status became evident

• First application of Moringa Inc. rejected based on objections raised by several member states

• In 2002, favorable opinion issued by EU Scientific Committee, based on assessment of extensive toxicity and allergenicity data. EU authorization of noni juice as novel food as of June 2003
Oca or “chioca” (Oxalis tuberosa) - rated as non-novel

- Introduced on UK market post-1997
- Food Standards Agency (UK competent authority): “oca is unlikely to fall within the remit of the NFR”
- Opinion based on occasional presence of oca in European gardens as “evidenced” in 19th century garden books
Impact of 258/97

• Confusion in developing countries, diverging practice of 258/97 within EU

• Chances of EU market admission for the majority of exotic food species are currently nil, unless extensive data allowing stringent food safety assessment are available

• Pioneering companies have been discouraged to invest in “novel”-traditional products

• **However:** much unawareness of the legislation in firms, development agencies and trade promotion organizations (UNCTAD, Biotrade, SIPPO)
Are the concerns overstated?

• Market size and potential of traditional exotic food to generate income for the poor overstated?
  – Trade still modest but growing (Biotrade)
  – Comparative advantages of the poor

• Exotic foods likely falling under the NFR, or even incriminated by it, continue to be marketed in the EU?
  – Lack of enforcement
  – Uncertainty of novel food status
  – Divergent implementation of NFR in member states

• Haven’t non-EU countries similar regulations to protect consumers?
Novel Food Regulation in Switzerland

Merkblatt zur Registrierung eines Neuproduktes gemäss Art. 3 Abs. 2 ff der Lebensmittelverordnung (LMV)

Vorbemerkung


Anforderungen

- Grundsätzlich sind die Bestimmungen der Lebensmittelverordnung einzuhalten, dies betrifft insbesondere auch die Bestimmungen bezüglich Zusatzstoffe, Pflanzen- und Getreideprodukte sowie die Hygienebestimmungen (LMV, RLM, Hau).
- Die Erstverkaufsmenge richtet sich in erster Linie nach den Artikeln 14, 34 der Lebensmittelverordnung (LMV) sowie den Bestimmungen der Lebensmittelverordnung (LMV).
- Die Produkte müssen sich deutlich von bereits aufgezählten Produkten unterscheiden.
- Wenn neue, noch nicht bekannte Substanzen oder Substanzen verwendet werden, müssen wissenschaftliche Daten eingereicht werden, die beweisen das die verwendete Substanz nicht gesundheitlich unbedenklich hat sich in Verwendung. In einem Lebensmittel gezeigt und keine von dem betroffenen pharzmeutischen Wirkung haben.
- Es muss der Nachweis erbracht werden, dass das Produkt unverkennbar zusammenhängt und die bislangigen Eigenschaften von welcher Art Guides durch ein wissenschaftliches deutsches wissenschaftliches vollständig ein LMV ein LMV die LMV.
- Das Produkt darf keinen Hauch irgendwelcher Anteile, die ihm Eigenschaften der Vorbeugung, Bekämpfung oder Heilung einer menschlichen Krankheit oder ihm eigenständig die kleinen Verpackung durch die Lebensmittelverordnung (LMV) enthalten.

Einunterlassende Unterlagen

Die fälligen Unterlagen müssen schriftlich per Post eingereicht werden. Voraussetzung dabei ist die Anforderung der spezifischen Unterlagen.

Ausführliches Format: "Bewilligungsurkunde gemäss Art. 3 Abs. 2 ff der Lebensmittelverordnung (LMV)" ist beispielsweise beim BAG, Section Lebensmittel, Postfach 2008 Bern oder über die Internet unter folgender Adresse: http://www.admin.ch/bag/act/lebensmittel/lebensmittelverordnung.html und
- Gemäss Text zeigt die genannten Muster schöner sind und den spezifischen Inhalt des Textes zu den angezeigten Zahlen, gegebenenfalls mit Unterlagenbeilagen.
- Verpackungsnachweise, möglichst in originärverpackung
- Eilverfahren des BAG oder andere mehrwährige physiologische Ernährungsstufen außerhalb werden, möglichst erste mehrwährige legen werden.
- Zusätzlich muß eine weitere Bewilligung des Lebensmittelrechtlichen Status im Zeitschrift, falls es sich um ein ausländisches Erzeugnis handelt (Adresse siehe unten)
Lobbying for Amendment

- IPGRI, GFU (Global Facilitation Unit for Underutilized Species), GTZ (German ODA), PhAction (Global Postharvest Consortium)
- Initiative supported by BMZ (German Ministry for Economic Cooperation and Development)
- Discussion paper submitted to, and discussed at, BMVEL (German Ministry of Consumer Protection and Agriculture)
Proposals for Amendment

• Recognition of exotic traditional foods as separate Novel Food Category

• Simplification of safety evaluation:
  - recognize indigenous knowledge
  - put in perspective of accepted EU foods
  - toxicity or clinical studies only where indicated

• Exotic traditional foods should remain in the public domain and no private entity be granted quasi-monopolistic marketing rights

• Clarify role of taxonomic and domestication status of food source
Outlook

• Food safety concerns must be addressed in the design of agricultural research and development projects
• Crop monographs needed that compile dispersed knowledge on intake levels, composition, traditional processing, etc.
• More emphasis on substantiation of traditional knowledge
• Assistance to developing countries to cope with non-tariff trade barriers