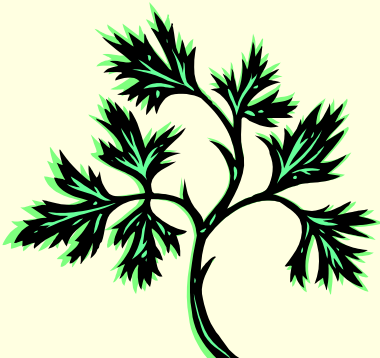


**GA Kiel**  
**3<sup>rd</sup> September 2003**

---

**EU Herbal Regulatory Issues  
for Workshop discussion**

**Maurice Hanssen  
President, EHPM**



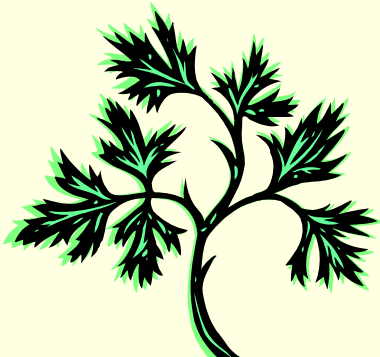
# EHPM

---

## The European Federation of Health Product Manufacturers Associations

Founded in 1975

21 Members from 17 Countries



# Each State has different:-

---

**Traditions**

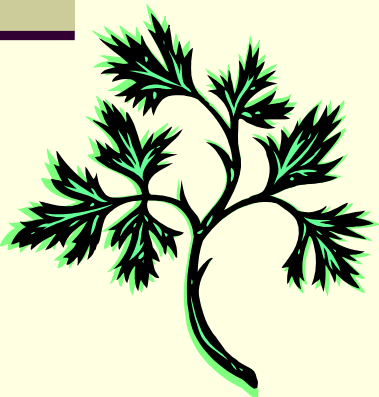
**Cultures**

**Existing laws**

**Market practices**

**Routes of sale**

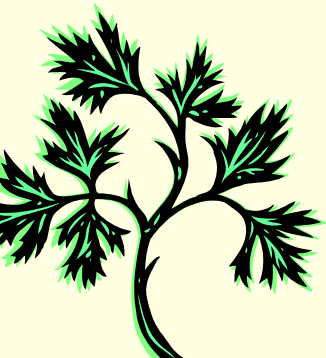
**so that no common system will be  
perfect for anyone**



# Therefore:

---

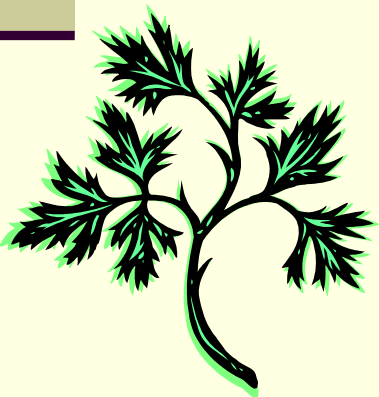
- **THMPD is generally supported but where are the solutions to:**
- **Changes in route of sale required if herbals become pharmaceuticals eg. Belgium, Italy, France**
- **Fossilisation of Herbal Medicines**
- **Herbs under Food Law**
  
- **We seek workable compromises**



# EU Directive 2002/46/EC

---

***“There is a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plant and herbal extracts.”***

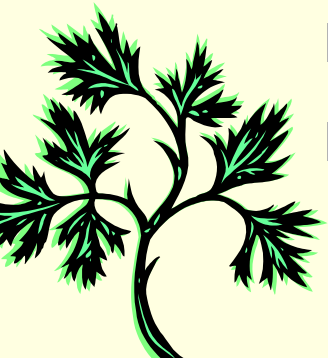


# Herbs under Food Law

## some options:

---

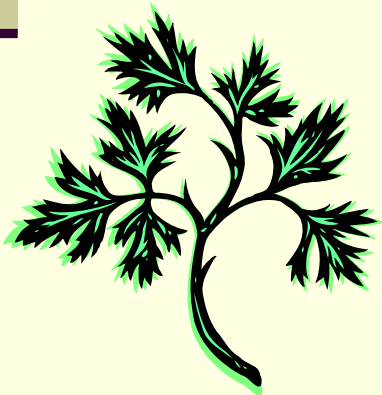
- Herbs and extracts with a history of safe usage as foods. Making health promoting/maintenance claims in accordance with the Food Supplements Directive
- Herbs at sub-therapeutic levels, as in Belgium
- An agreed list, as in Italy
- National solutions for internal markets
- A negative, not a positive list



# Consumers demand under Food Law:-

---

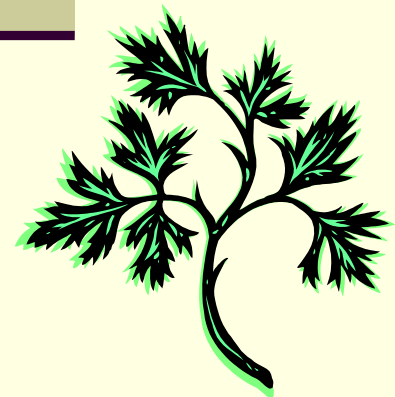
- Quality (HACCP)
- Traditional safety (as in THMPD)
- Informative labelling
- A wide freedom of choice
- No route of sale restrictions



# Medicinal Options:-

---

- Defined medical purpose
- Dosage with clear medicinal effect
- Medicinal claim
- Traditionally used – THMPD
- Well established – Registration

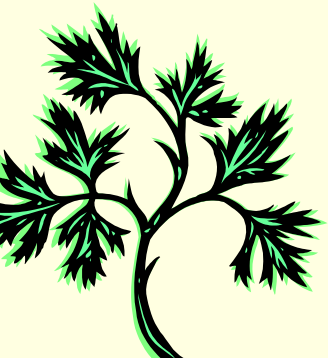




# We need:-

---

- **Herbs as medicines**
- **Herbs as foods**
- **Herbs as food supplements**
- **Unrestricted routes of sale**
- **Quality**
- **Traditional safety**
- **Appropriate claims**



# THANK YOU

---

**I NOW LOOK  
FORWARD TO THE  
ANSWERS!**

