



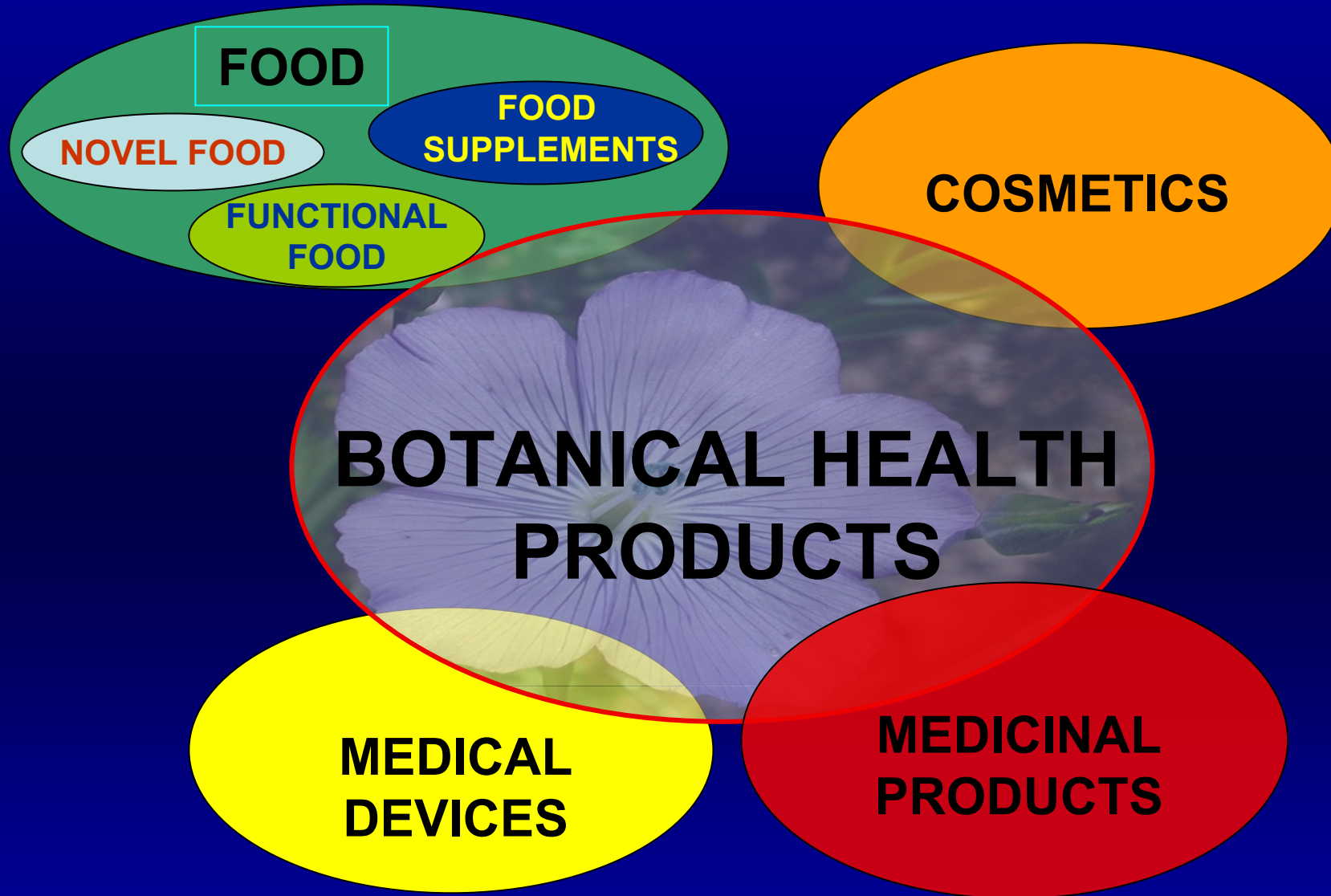
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# **PROGRAMME**

- 1. INTRODUCTION**  
**A.J. VLIETINCK, UNIVERSITY OF ANTWERP (UA), BELGIUM**
  - 2. EUROPEAN REGULATOR'S PERSPECTIVE ON IMPLEMENTATION**  
**K. KELLER, HMPC, EMEA.**
  - 3. NATIONAL REGULATOR'S PERSPECTIVE ON IMPLEMENTATION**  
**H. PITTNER, AGES PHARMMED, AUSTRIA**
  - 4. PHYTOTHERAPEUTICAL ASSOCIATION'S PERSPECTIVE ON IMPLEMENTATION**  
**B. STEINHOFF, ESCOP, AESGP**
  - 5. VIEWPOINT OF THE PHARMACEUTICAL INDUSTRY**  
**B. ROETHER, REGULATORY AFFAIRS, BIONORICA AG**
  - 6. VIEWPOINT OF THE PRODUCERS OF FOOD SUPPLEMENTS**  
**P.COPPENS, EUROPEAN BOTANICAL FORUM (EBF)**
  - 7. WILL THE COMMUNITY MONOGRAPHS AND LIST ENTRIES OF THE HMPs BE  
HELPFUL FOR A SUCCESSFUL APPLICATION TO A REGULATORY AUTHORITY?**
  - 8. CONCLUSIONS**  
**S.ALBAN AND A.J. VLIETINCK**
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# LEGAL STATUS OF HERBAL PRODUCTS WORLDWIDE



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# EUROPEAN HARMONISATION FOR HERBAL MEDICINAL PRODUCTS

- EUROPEAN PARLIAMENT
- EUROPEAN COUNCIL
- EUROPEAN COMMISSION
- EUROPEAN PHARMACOPOEIA
- EUROPEAN AGENCY FOR MEDICINAL PRODUCTS, EMEA
- NATIONAL AUTHORITIES OF EU MEMBER STATES
- INDUSTRY E.G. AESGP WORKING GROUP
- SCIENTIFIC ORGANISATIONS, E.G. ESCOP

INTERNATIONAL SOCIETY FOR MEDICINAL PLANT  
RESEARCH, GA

EUROPEAN SOCIETY OF ETHNOPHARMACOLOGY

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# THE EU PYRAMID OF PERMITS FOR HERBAL PRODUCTS

## PRODUCTS

### \* HERBAL MEDICINAL PRODUCTS (HMPs)

- FULL MARKETING AUTHORIZATION
- WELL ESTABLISHED USE HMPs (WEU)
- TRADITIONAL HMP (THMPs)

### \* HERBAL FOOD SUPPLEMENTS

### \* HERBAL NOVEL FOODS

### \* HERBAL COSMETIC INGREDIENTS

## LEGISLATION

### \* MEDICINAL PRODUCTS

CD 2001/83 EC AS AMENDED BY  
CD 2004/24 EC AND 2004/27 EC

### \* FOOD SUPPLEMENTS

CD 2002/46 EC

### \* NOVEL FOODS

REGULATION 258/97

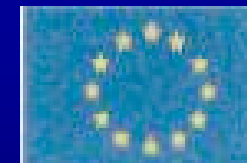
### \* COSMETICS

CD 76/768

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# DIRECTIVE 2004 / 24 / EC ON TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMPs)



## \* TASKS OF THE HERBAL COMMITTEE (HMPC)

- ESTABLISH A LIST OF HERBAL SUBSTANCES, PREPARATIONS AND COMBINATIONS THEREOF FOR USE IN THMPs
  - ESTABLISH COMMUNITY HERBAL MONOGRAPHS FOR WELL-ESTABLISHED MARKETING AUTHORISATIONS OR TRADITIONAL REGISTRATIONS OF HMPs.  
MONOGRAPHS SHALL BE USED AS THE BASIS FOR ANY APPLICATION
  - AT THE REQUEST OF A MS DRAW UP AN OPINION ON THE ADEQUACY OF THE EVIDENCE OF THE LONG-STANDING USE
  - BE RESPONSIBLE FOR ARBITRATION / REFERRAL PROCEDURES ON THMPs
  - GIVE AN OPINION ON OTHER MEDICINAL PRODUCTS CONTAINING HERBAL SUBSTANCES REFERRED TO THE EMEA/CPMP
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