ROMANIAN MEDICINAL AND AROMATIC PLANTS

a valuable natural bio-resource

3700 wild species of registered higher plants

324 species scientifically proved to have therapeutic properties

100 - 200 species of tinctorial value containing bio-degradable pigments

180 species used at industrial scale

80 species identified as toxic

Traditional herbal medicines, pharmaceutical products for human and veterinary use

40 species containing tannins and resins

Different other industries

Food coloring, additives, hair care products, natural dyeing

Over 800 species traditionally used as medicinal
Romanian market of herbal products was always supported by the consumers' confidence in their efficiency.

Romanian industry might face to the competition of the new products entering the market, especially after 2007 year, when Romania joined the EU.

Local industry had to invest in modern equipment, GMP or HACCP certification, current training of the employees (IFS), research and development, innovation and new product formula.

There are registered near 160 production units of herbal food supplements, most of them being SMEs.

Romanian products cover 35-40% of the whole market of herbal products; they are sold by different distribution channels, including on-line.

Favorite products are herbal teas, food supplements, culinary spices, traditional medicine products.

Consumers are attracted due to low price, natural origin, tradition of use, no side effects, easy access (no medical prescription).
Total number of herbal food supplements on the market

March 2015 – **18 252 products**

Annually rate of new products notification - **1500/year**

Vitamins and minerals – **2 896 products**

Medicinal plants – **8 037 products**

Plant extracts and others – **10 215 products**
FOOD BUSINESS OPERATORS AND DISTRIBUTION CHANNELS FOR THEIR PRODUCTS

Territorial coverage

Distribution Channels

- Drug stores
- Supermarkets
- Fitness clubs
- Sex shops
- Specialized shops (natural products)
- web-sites
- tele-shopping
- Individual dealers
- Local news papers
- Medical offices
NATIONAL LEGAL FRAMEWORK

• Law 491/2003 of Medicinal and Aromatic Plants
• Ministry Decree 244/2005 – regarding herbal food supplements, processing and trading of medicinal and aromatic plants
• Ministry Decree 1228/2005 – regarding trading of food supplements having in composition other substances than minerals and vitamins
• Ministry Decree 111/2008 – regarding production activities, processing, storage, transport and marketing of food of non-animal origin
• Government Decision 732/2011 – implementation of Reg. 1924/2006 on nutrition and health claims
• Ministry Decree 1705/2011 – regarding nutritional and health claims claim control of foodstuff
• Ministry Decree 1946/2014 – Procedure of herbal food supplement notification of SNPMAPS
ORGANIZATION CHART

NATIONAL OFFICE FOR MEDICINAL PLANTS AND BEE PRODUCTS (SNPMAPS)

NOTIFICATION DEPARTMENT
- FOOD SUPPLEMENT
- HEALTH CLAIMS VALIDATION
- TOPIC PRODUCTS

DATABASE
- www.bioresurse.ro

SURVEILLANCE AND CONTROL DEPARTMENT
- PRODUCTION LINES AND WAREHOUSES
- INFORMING SEMINARS
- PRODUCTS QUALITY AND SAFETY ANALYSES

RANGE OF SERVICES
- notification
- consulting
- technical assistance
- product monitoring
- production line control
- tests and trials
- product analyses
- informing seminars
- scientific research
- database management

PARTNERS
- LOCAL INSPECTORS
- HUMAN RESOURCES DEPARTMENT
- OWN LABORATORIES OF IBA
- IBA’S PARTNERSHIP WITH OTHER LABORATORIES
USE OF IBA INFRASTRUCTURE

Packaging laboratory
Heavy metals: Pb, Cd, Hg, St

Physico-chemical laboratory
Ash, Humidity, Dry residue, Density, Refractive index, Acid index, Iodine index, Peroxide index, Disaggregation time, Sugars

Microbiology laboratory
Total number of germ, Yeast, Molds, Bacteria

Sensory analysis laboratory
Volatile compounds determination

HFS MATRICES

SOLID
- HERBAL TEAS
- POWDER
- CAPSULES
- TABLETS
- GRANULES
- BARS

LIQUID
- OILS (FAT, ESSENTIAL)
- PLAN
- EXTRACTS (ALCOHOLIC, GYCERIN, AQUAOUS)
- SYROPS

Nuclear Magnetic Resonance Spectrometer
BRUKER DRX 400 MHz

Calcinations furnace
NABERTHERM

MULTISENZOR SISTEM α-PROMETHEUS

MICROFOSS

ICS3000 – ion chromatograph

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Heavy metals: Pb, Cd, Hg, St

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ICS3000 – ion chromatograph
I. PROCEDURE OF NOTIFICATION

- Notification of herbal food supplements is compulsory before product enter the market
- National Register of herbal food supplements is of public interest and can be accessed on the website www.bioresurse.ro
- Notification authorities belong to the Ministry of Agriculture (SNPMAPS) and Ministry of Health (CRSP)
- Notification dossier includes documents regarding the manufacturer and country of origin, product presentation (composition, packaging, labeling), proofs of quality and safety (physic and chemical analyses, microbiological tests) both for ingredients and final product
- A sample of the product must accompany the dossier and specific analyses/tests have to be done when suspicion of non-compliance arise
- Technical Committee has the right to exempt certain products (derogation from national rules)
- Mutual recognition regulation (CE) no. 764/2008) is applied for EU products (art. 2, art.6)
LABELING IN ACCORDANCE WITH NEW REGULATION

Etichetarea si re-etichetarea suplimentelor alimentare in 2014

- Produse nou intrate pe piata, etichetate conform noilor reglementari comunitare in 2014: 76%
- Produse notificate anterior, ale caror etichete au fost revizuite si reformulate in 2014: 24%

LABELS
1545 new entered products
430 old products
New labels

PRODUCTS
874 Ro
210 EU
891 non-EU
CONSUMERS INFORMATION BY LABELING

UNDECLARED INGREDIENTS
(forbidden substances)
- spectacular physiological effects

SIDE EFFECTS
- adverse
- cumulative
- allergic reaction

HEALTH CLAIMS
- not scientific substantiated
- not authorized in UE by EFSA
- forbidden on food product

MISSING INFORMATION
- traceability info (producer)
- list of ingredients
- recommendation of use

NO WARNING
- diet interaction
- drug interaction
- forbidden for sportsmen (doping)
- vulnerable categories
- intolerance

NO EFFICACY
- Biologic active compounds under the minimum level
- Substitution of efficient species by phenotypic similar ones
- Fillers instead of concentrated plant extracts (wheat, soybean, rise)
II. MANAGEMENT OF CLAIMS PROPOSALS AND VALIDATION

BOTANICAL AND PLANT EXTRACTS

- Many species
- Different parts used
- Infinite combinations
- Synergistic/antagonistic action
- Secondary metabolites (min-max values)
- Dietary habits
- Traditional use

NUTRITION AND HEALTH CLAIMS

- Authorized claims
- ‘On hold’ claims
- Specific evaluation criteria
- Lack of EU harmonization
- Physiological effects
- Recommendation of use & warning

APPLICATION OF EU REGULATION

- Reg. (CE) no. 1924/2006
- Reg. (CE) no 1925/2006 (art. 8)
- Dir. 2002/46 (CE)
- Dir. 2008/100, annexes I si II
- Reg. (EU) no 432/2012, alin 10, 11
- Reg, 1169/2011, annex XIII

REFERENCE DOCUMENTS AND REPORTS USED IN EVALUATION

- Compendium of botanicals, EFSA, 2012
- Use of other substances than vitamins and minerals, EAS, 2007
- Guidance on safety assessment of botanicals and botanical preparations, EFSA, 2009
III. MARKET SURVEILLANCE AND CONTROL

Product conformity is checked when existing:
- a non-compliance suspicion (expressed by SNPMAPS during the notification dossier evaluation or sample examination)
- a consumer complaint (safety concern, lack of effect, side effects)
- an alert (expressed by another national authority)
- a rapid alert (EU via national Agency for Food Safety, EFSA contact point)
- a specific demand (other operators, Customs Authority, lawyers)

Most problems encountered were related to:
- product authenticity (falsified products were discovered on the market)
- illegal trade (product was not notified)
- plant substitution (another species was declared)
- quality and safety of raw material (contamination, no confident suppliers)
- adulteration (pharmaceutical substances were found in the composition of food supplement)
- labeling and advertising (unauthorized health claims)
LABORATORY TEST RESULTS

Confirmarea / infirmarea suspiciunilor in urma analizelor si testelor de laborator efectuate

- 83% Confirmate
- 17% Neconfirmate

2013

Rezultatul anchetelor in ceea ce priveste suspiciunea de neconformitate a mostrelor de produs analizate

- 86% Confirmarea suspiciunilor
- 14% Neconfirmarea suspiciunilor

2014
ON-LINE

TV ADVERTISING, TEleshopping, HIDDEN PROMOTION IN TV SHOWS

HEALTH CLAIMS USED FOR PRODUCT PROMOTION AND ADVERTISING

PHARMACY
DRUG STORE

Modul de utilizare al mențiunilor nutritionale si de sanatate - Compartimentul Supraveghere si control: verificarea produselor comercializate in farmaci

- Mentiu nutritionale neconforme: 89%
- Mentiu de sanatate neconforme: 11%

Modul de utilizare al mențiunilor nutritionale si de sanatate - Compartiment Supraveghere si Control: verificarea produselor comercializate on-line

- Mentiu de sanatate interzise (nume de boli, proprietati terapeutice): 48%
- Produse comercializate ilegal (fara a fi notificate): 52%

- Canal TV care au difuzat spoturi publicitare purtatoare de mesaje inselatoare: 56%
- Canal TV care practica publicitatea mascata: 33%
- Canal destinat preluiarii de comenzi (teleshopping) care promoveaza produse cu mențiuni de sanatate interzise: 11%
COOPERATION WITH OTHERS
AUTHORITIES

- MINISTRY OF HEALTH: ‘border’ products or ingredients (registered as medicine/drugs in some MS but as food supplements in others); novel food ingredients; product composition control; alerts
- ANTI-DOPING AGENCY: list of forbidden substances in food supplements used by sportsmen (botanicals as hormones precursors)
- CONSUMER PROTECTION AUTHORITY: labels and claims (incomplete information)
- AUDIOVISUAL COUNCIL: health claims in advertising and product presentation in media
- NATIONAL FOOD SAFETY AUTHORITY: safety control at the borders (Customs); rapid alerts
- JUSTICE AND POLICE: illegal trade, food fraud
THANKS FOR YOUR ATTENTION!