

53rd ANNUAL CONGRESS
Society for Medicinal Plant Research

***Good Agricultural Practice
and
Good Wildcrafting Practice,
present and future.***

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GAP (Good Agricultural Practices) : Precedents


- **1983** First initiatives for the elaboration of GAP - Angers, France (1)
- **1988** Conference on Medicinal Plants - Novi Sad, Serbia (2)
- **1989** International Society for Horticultural Sciences (ISHS) - Budapest, Hungary (3)
Máthé: *"Biological aspect of GAP - Guidelines. Cultivation"* - Newsletter of Medicinal and Aromatic Plants Budakalász (4)
- **1991** Pank, Franz, Herbst: *"Richtlinien für den intergrierter Anbau von Arznei-und Gewürzplanzen"* - Drogenreport (5)
- **1992** World Congress on Medicinal and Aromatic Plants for Human Welfare (WOCMAP) - Maastricht, Holland (6)
- **1995** Permanent Commission for Breeding and Cultivation of the Society for Medicinal Plant Research (GA) - Halle, Belgium (7)

GAP (Good Agricultural Practices) : Precedents

- 1998 5th August First draft of EUROPAM (EHGA) GAP (Good Agricultural Practices) -
- 1999 EMEA Draft Comments on the EUROPAM GAP of August 5, 1998
- 2000 First EUROPAM (EHGA) version of GWP (Good Wild crafting Practices)
- 2002 EMEA published “Points to Consider on Good Agricultural and Collection (GACP) Practices for Starting Materials of herbal origin” - EMEA/HMPWP/31/99/Rev. 3
- 2003 WHO releases the final version of “Guidelines on Good Agricultural and Collection (GACP) Practices for Medicinal Plants”
- 2005 EMEA published “Public Statement on Good Agricultural and Collection Practices for Starting Materials of herbal origin” - EMEA/HMPC/246816/2005

GAP by EUROPAM (EHGA)




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- 1998 - GAP First Version →
 - 1999 - Working Copy N. 1
 - 2000 - Working Copy N. 2
 - 2001 - Working Copy N. 3 and N. 4
 - 2002 - Working Copy N. 5
 - 2003 - Working Copy N. 6 and N. 7

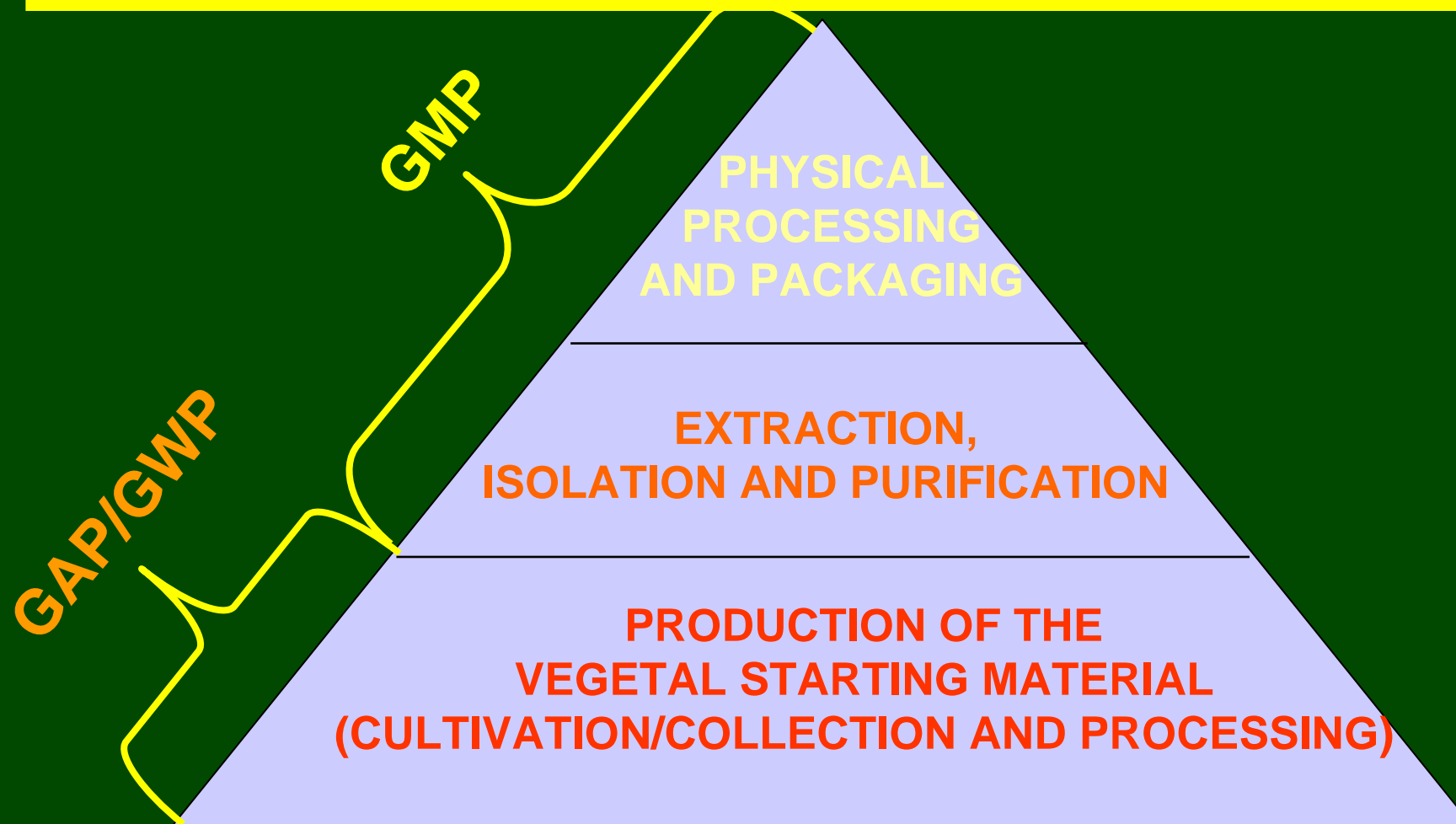
EMA “*Point to consider...*” 2002:
“*Public statement on...*” 2005

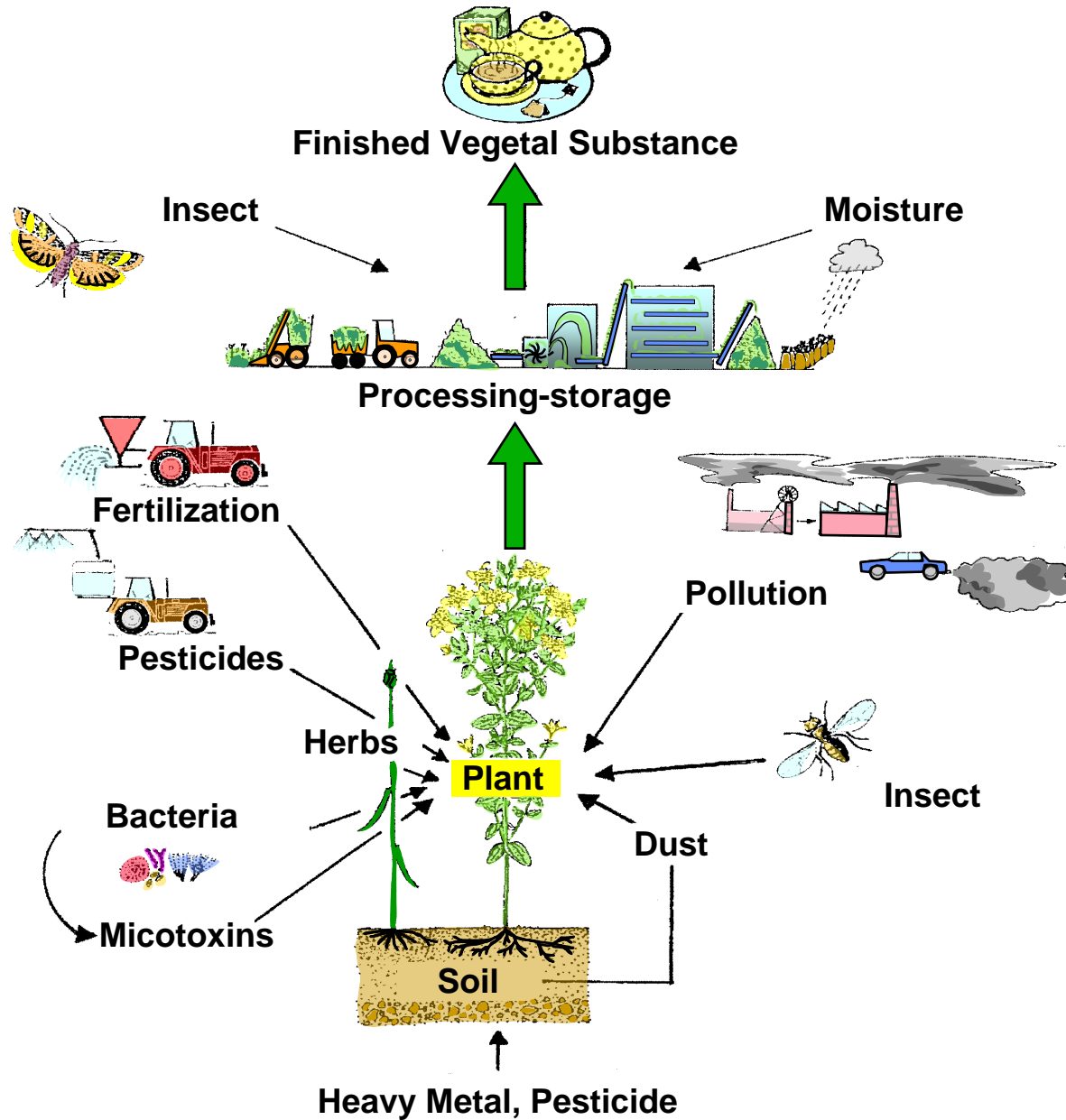
GWP by EUROPAM (EHGA)



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- **2000 - Working Copy N. 1**
 - **2001 - Working Copy N. 2 and N. 3**
 - **2003 - Working Copy N. 4 and N. 5**

API OF VEGETAL ORIGIN





Vegetal Substance Production

Criticism

- **Insufficient or changeable quality standard level**
- **Lack information and control concerning the use of Plant Protection Products**
- **Risk of Pesticide residue and contamination (Micotoxins, Bacteria, Heavy Metals)**
- **Lack of traceability**
- **Lack of, at least basic, Production Quality Assurance System**
- **Over-harvesting, uncontrolled collection, over-exploitation**

What does mean to follow fully with GAP/GWP ?

- To be conscious of:
 - the critical steps
 - the risks to produce insufficient quality
 - the risk of residue and contamination
 - the risk of unsustainable wild collection
- Ensure constant high quality and safety standard level
- Ensure the full traceability of the production and record keeping
- To establish, at least basic, Production Quality Assurance System

GAP in the World

Europam

EMEA

WHO

Korea

Japan

China

USA



2005

GAP Protocol



GACP (WHO) Differences

- Ethical and legal consideration
- Intellectual property right and benefit-sharing
- Threatened and endangered species
- Environmental aspects
- Ecological environment and social impact for cultivation
- Technical planning for wild collection

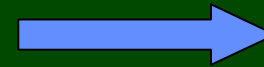
**But how does the buyer of
vegetal substance know
that the guidelines are
being fully followed?**

AUDITS

= systematic and independent examinations of a system to determine whether the vegetal substance safety, quality and related management activities are undertaken in accordance with the documentation, to determine compliance with the requirements and verify that these arrangements are implemented effectively.

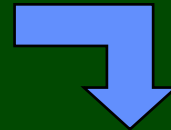
TYPES OF AUDITS

- **Supplier on supplier
(internal Audit or self-
inspection)**



NOWADAYS

- **Buyer on supplier
(external Audit)**



2003: FAH - SOP



NOWADAYS

- **Independent third
party (external Audit)**



THE FUTURE?

INDEPENDENT THIRD PARTY AUDITS

- **Conducted by person not associated with supplier or customer**
- **Audit for compliance with a predefined and accepted standard**
- **Auditor should have experience with the commodity and processing being audited**
- **Possibility to issue an independent certification**

Which Standard ?

(Which guidelines could become a Standard?)

EUROPAM (GAP/GWP)

EMEA (Public Statement on...)

WHO (GACP)

Or other...or a compromise of them.

CERTIFICATION

Who will take advantage of it ?

- **The quality:**
 - No zero risk of poor quality
 - It can assure that appropriate programs are in place to minimize the risk
- **The small size buyer:** it facilitates the choose of the right supplier
- **The large size buyer:** reduces the cost of the auditing, contaminant control, supplier qualification procedure
- **The market:** positive impact on Consumer confidence
- **The producers:** reducing of the criticism and resistance by Health Authorithies, reinforced by negative media blitz

Thank you for the attention

Renato Iguera