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Major Constraints for Trading Herbs in the EU:
Saffron as a Cash-Crop with Potential on the EU Markets

International Buyer-Seller Meet on
Herbal & Medicinal Plants
New Delhi, October 28, 2007

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Topics

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a) General EU-regulations for herbs

→ Quality and Traceability: Directive 178/2002/EC

→ Health Claims: Directive 1924/2006/EC

→ Novel Food regulation 298/97/EC

→ Traditional Medicinal Plant Directive 2001/83/EC

Topics

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b) Practical example: Saffron as a potential cash-crop

→ Traditional uses and modern research

→ Recent galenical developments

→ Current saffron markets and qualities

Directive 178/2002/EC

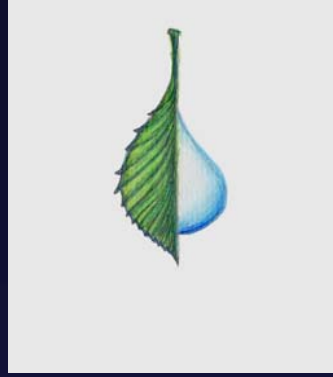
Article 18: Traceability

The traceability of food and any other substance intended to be, or expected to be incorporated into a food shall be established at all stages of production, processing and distribution.

→ **The origin of the plant material must be known!**

→ **Based on WHO GACP Guideline**

Health Claim Directive 1924/2006



- → Food supplements intended to be marketed with a “Risk reduction claim” need an authorization
- → The application is very similar to that of a drug application
- → Quality examinations such as stability testing are mandatory

Novel Food Regulation 298/97/EC

- → Food plants not available on the market prior to 1997 are considered "Novel"
- → Registration procedure required
- → Focus on toxicology

Examples

Various plants of Indian origin are considered “Novel Food”, such as

Momordica charantia (Bitter melon)

Oryza sativa (Rice bran oil)

Teminalia arjuna (Arjuna myrobalan)

Phyllantus emblica (Amla)

Safety Data

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Novel Food status requires toxicological data demonstrating safety:

- **Allergenicity in vivo (?)**
- **Acute and chronic toxicity (in vivo)**
- **Reproduction toxicity (in vivo)**
- **Mutagenicity (in vitro/in vivo)**

Toxicology

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- Toxicity studies by a GLP-certified lab

- Rather costly (approx. 200.000 €)

- Investment opens the market for everybody

→ No economic interest by EU companies!

➔ Toxicity studies should be made by the producing countries who want to save and develop their agricultural markets!

Specific problems

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Problem:

Rejection of products labelled with "Ayurvedic Medicine" by the EU customs!

Reason:

The labelling of a product exported to the EU is a decisive factor for the legal status of a product!

Drug status

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Registration required:

- Full registration for unknown compounds

- Simplified as “Well established” for herbs where there is clinical experience

- Simplified as “Traditional” where such a tradition can be demonstrated.

Traditionally used…

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Means:

- At least 30 years of considerable (?) use, with at least 15 years within the EU

- Stability data required

- Toxicological data to be presented with the application:

→ Special attention on reproductive toxicity!

A practical approach: Saffron (Crocus sativus)

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Saffron – one of the world‘s most expensive spices

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Dried stigmates of *Crocus sativus* L.

→ Handpicked from the fresh flower

1 kg of saffron corresponds to 150.000 flowers!

World market price approx. 500-1.500 €/kg

Saffron harvesting and processing

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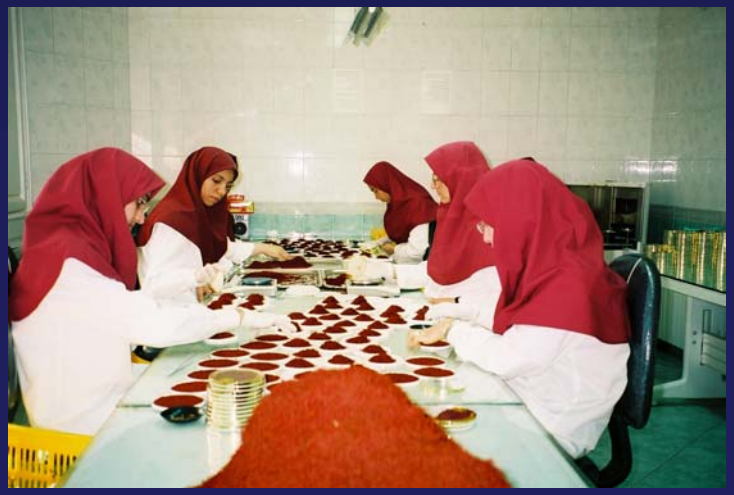

Saffron harvesting and processing

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Saffron harvesting and processing

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Traditional uses of saffron

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→ Use as a spice for cooking, far-spread in the Mediterranean contries

→ Valued as a medicinal plant from Antiquity to date

→ Traditionally used as a nervine (stimulant and aphrodisiac, anti-depressant)

→ stimulator of circulation

→ palliative tumour treatment

Saffron in modern research

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Confirmed in pharmacological studies:

→ Selective anti-tumour effects

→ Stimulant, anti-depressant and memory-enhancing effects

→ Blood lipid lowering effects

➔ Active constituents: safranals, crocins

Saffron in modern research

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Confirmed in clinical double-blind trials:

→ **antioxidative effects**

→ **antidepressant effects against placebo, imipramine and fluoxetine**

→ **To date no major adverse effects known from clinical trials and traditional experience**

➔ **Galenical forms under development!**

Recent galenical developments

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- ✓Development of saffron extracts and galenical forms for use in food, drugs or cosmetics
- ✓ Development of quality control tools based on the requirements for drug registration

Heavy metals	Ph. Eur. 2.4.27	Microbiology	Ph. Eur. 2.6.12-13
Residual solvents	In-house	Adulterants	AFNOR
Pesticides	Ph. Eur. 2.8.13	Stability	NTA
Aflatoxins	In-house	Specific assays	In-house

Extract types already developed

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- ✓ Full extracts standardized to active compounds such as safranal or crocins
- ✓ Extracts applicable in hydrophilic or lipophilic systems such as creams (cosmetic use) or liquids
- ✓Extracts on neutral carrier materials for the manufacture of solid forms such as tablets or capsules/microcapsules

Ongoing activities

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- ✓ Continuation of botanical screening and selection program
- ✓ Continuation of running stability testing of extracts
- ✓ Development of registration dossiers and special formulations for drug, food and cosmetics use

➔ Saffron has a bright future – provided there is no issue about safety due to bad quality!

Adulterations

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The high price invites fraudulent adulterations:

According to diverse screenings up to 90% of commercial saffron adulterated!

→ falsified origin to justify higher prices

→ pre-extracted saffron

→ weight-increasing materials (e.g. glycerol)

→ strips of red-coloured flowers

→ meat fibres, coloured gelatine fibres

→ coloured paper strips, threads of anilin dyes

New threats to rational use

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→ Antimicrobial treatment by irradiation

→ Use of pesticides and herbicides on new cultivation sites where saffron did not formerly exist

→ Lack of traceability of herbal raw material

➔ Compliance to European food and drug regulations required for saffron-based supplements or medicinal products!

Current markets and qualities

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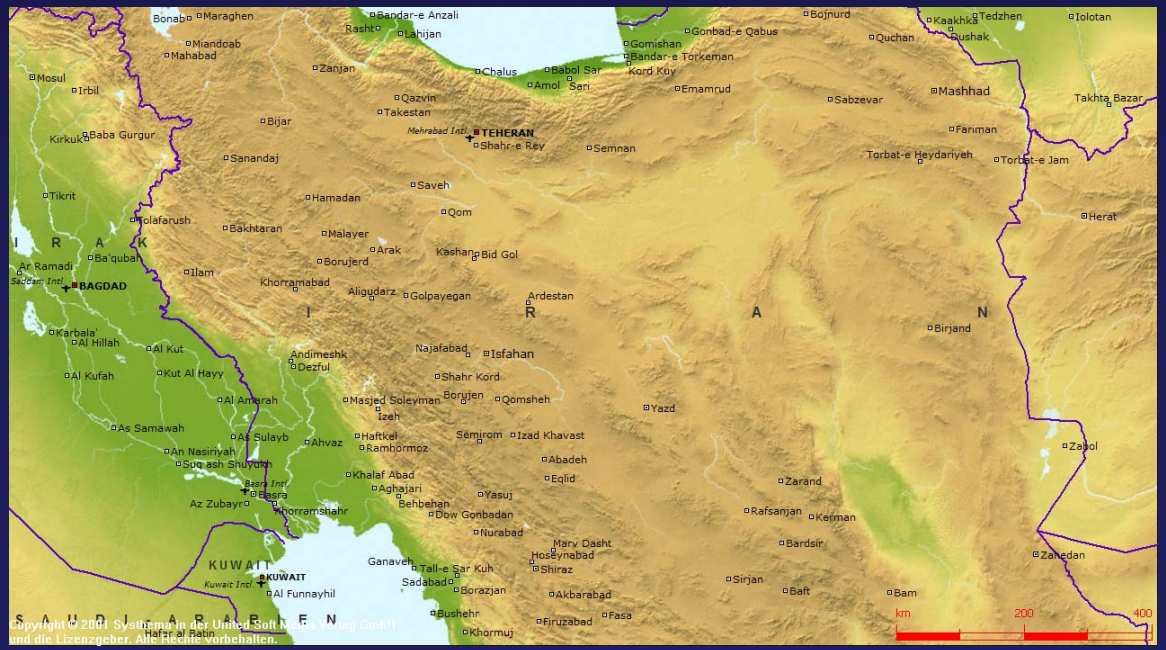
Iran:

- >85% of world production of saffron
- Good qualities in place



But:

High degree of blending and adulterations through activities of middle-men!

Azerbaijan, Turkey:

- New cultivation surfaces
- More saffron exported than produced!

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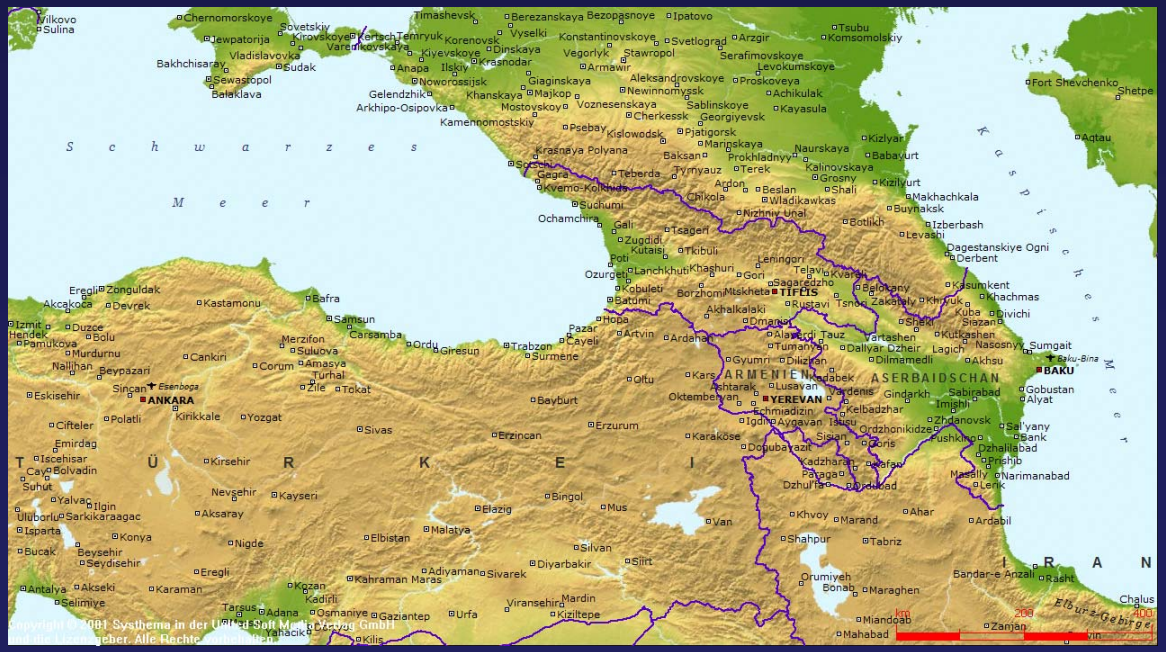

→ Blending with saffron of Iranian origin obscures traceability

Afghanistan

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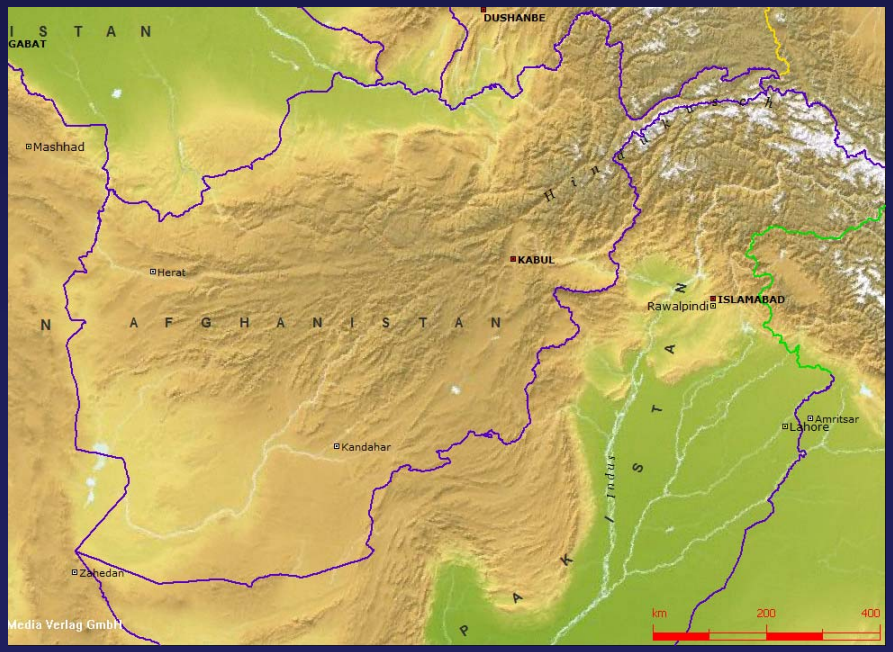
- Ancient production sites
- New surfaces under development



But:

- Exports via Iran as Iranian saffron
- Newly introduced cultivars not necessarily adapted to the climatic conditions

China

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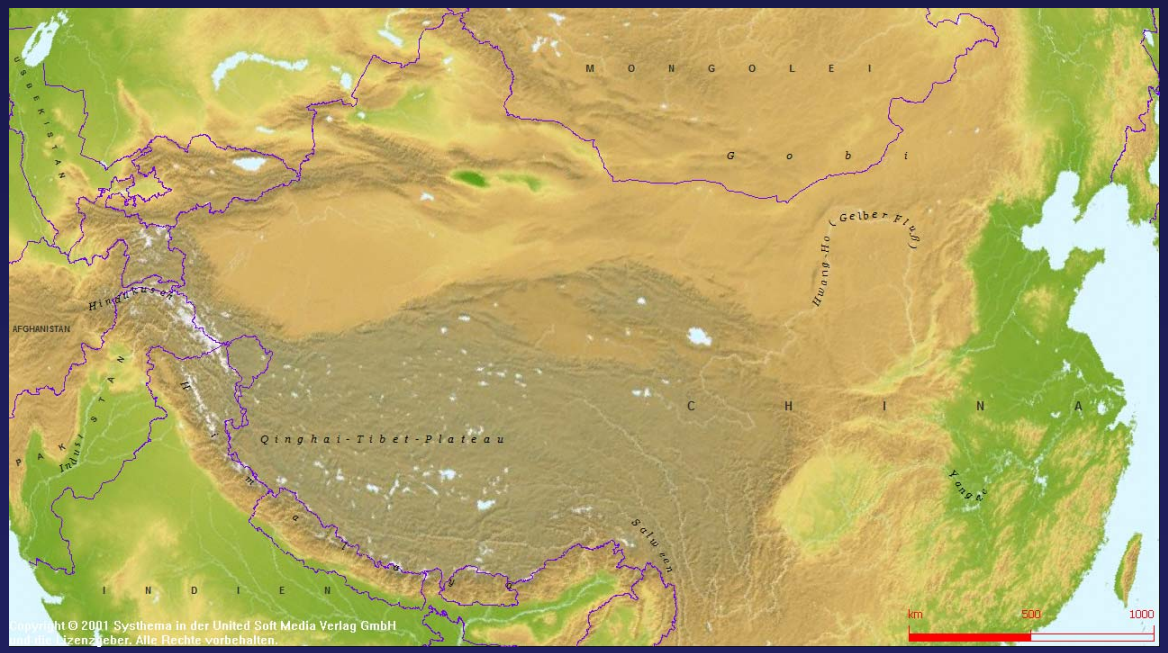
- Saffron traditionally held in high esteem
- New cultivation sites, strongly developing

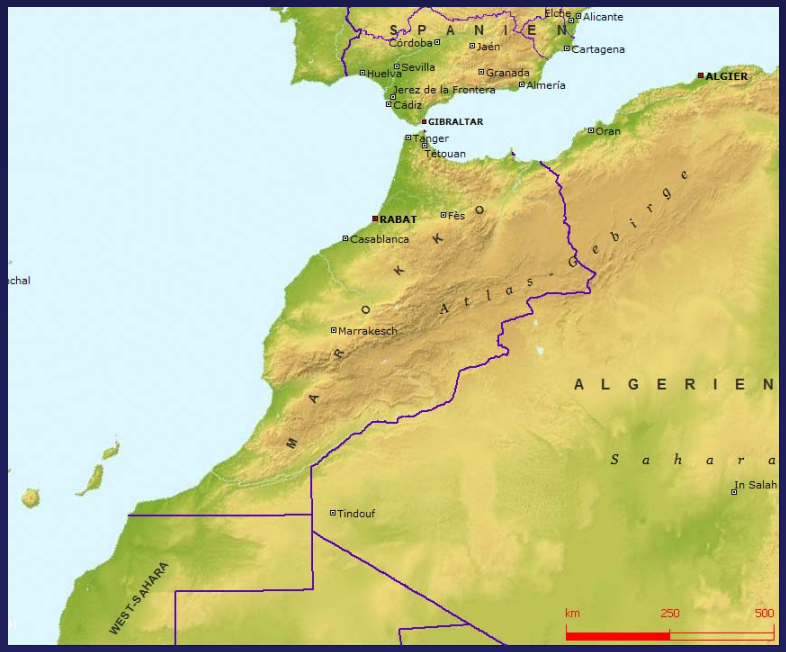


But:
- No traceability
- Systematic adulterations
- Problems with contaminants

→ Material often unsuitable for medicinal purposes

Morocco

- Developing surfaces
- Exports to Spain



But:

- Blending with material imported from Iran
- World market material untraceable

Italy, Greece, Switzerland

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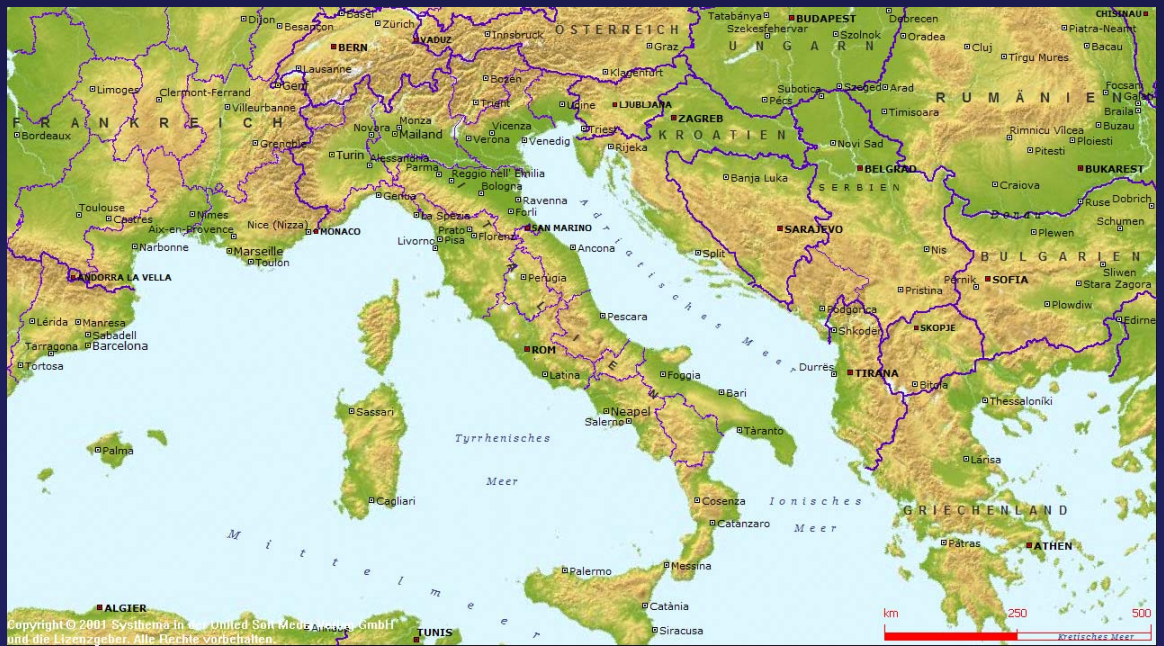
- Small surfaces, good quality
- Recent developments in Greece (current production approximately 4 tons/year)

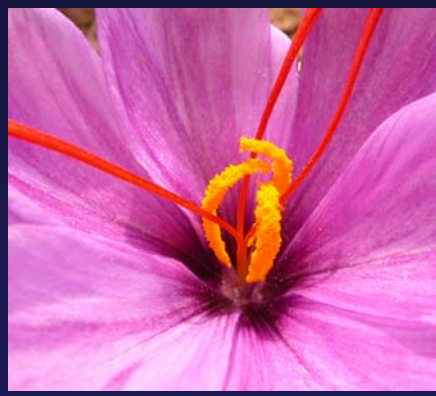


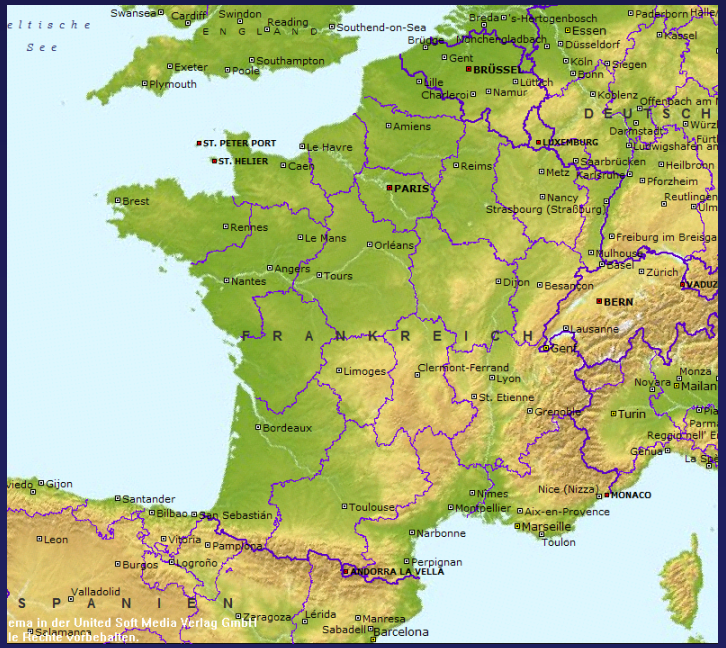
But:

- Competition on world market difficult because of high labour costs

France

- Ancient cultivations
- New surfaces under development
- Production does not cover local demand: Imports!





But:

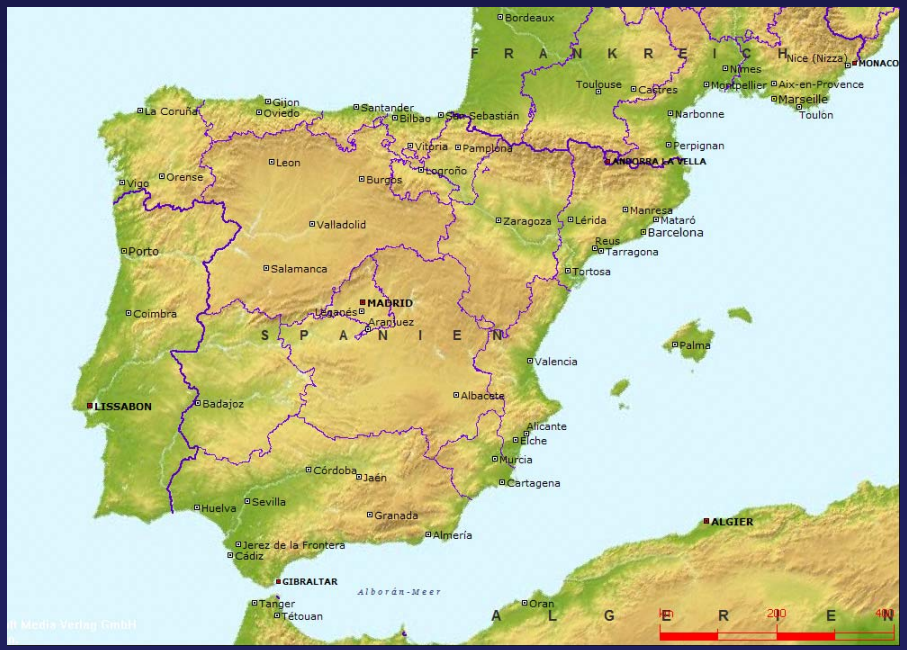
- High labour costs
- New cultivations with uniform types from specialized breeders

→Loss of biodiversity

→ Quality deviations in >80% of controlled samples of imported saffron

Spain

- Main exporter in Europe (approx. 60 tons/year)
- Production surfaces constantly decreasing
- Exports by far surpass own production (approx. 400 kg/year)!

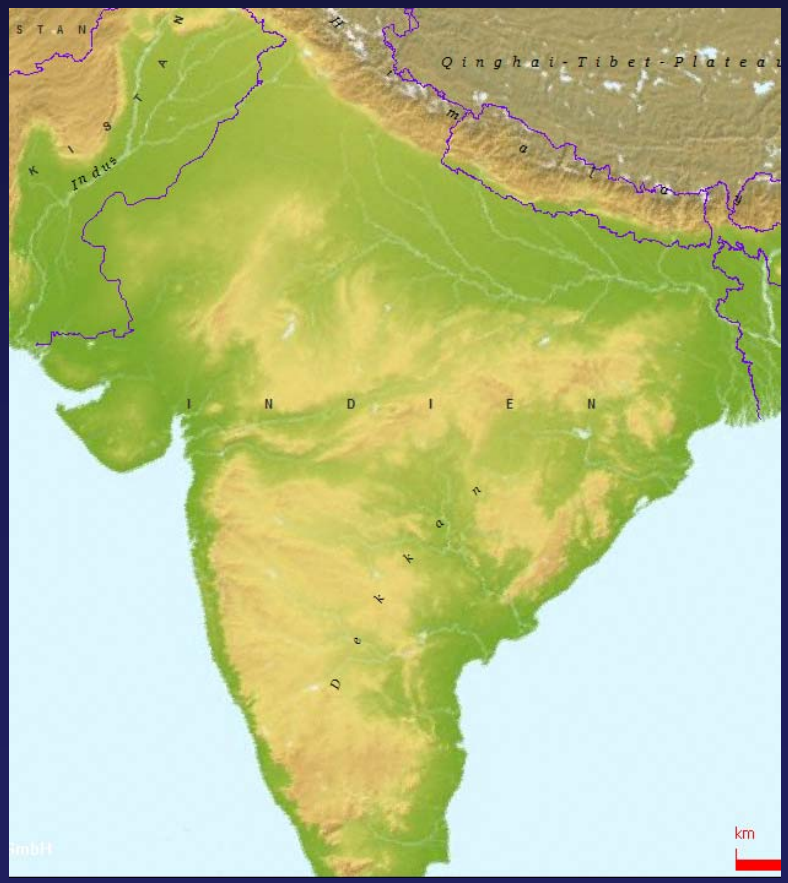


But:

- Current investigation of economic fraud of certain traders by French government!

India

- Increasing cultivation surfaces
- Good qualities e.g. from Kashmir and Srinagar



But:

- In some cases use of irradiation and non-EU-permitted herbicides and pesticides!

Conclusions

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- India has a good potential for developing saffron
- The EU and international markets are still growing
- Material adhering to EU regulations is highly welcome
- Saffron needs know-how in cultivation, but if successfully grown, is almost a self-seller!

- Pharmaceutical use of saffron requires special attention to quality parameters and drying techniques according to the constituent used for standardisation

➔ **We are happy to provide the necessary know-how for qualities acceptable to EU standards!**

Thank you for your attention

Georges Betti

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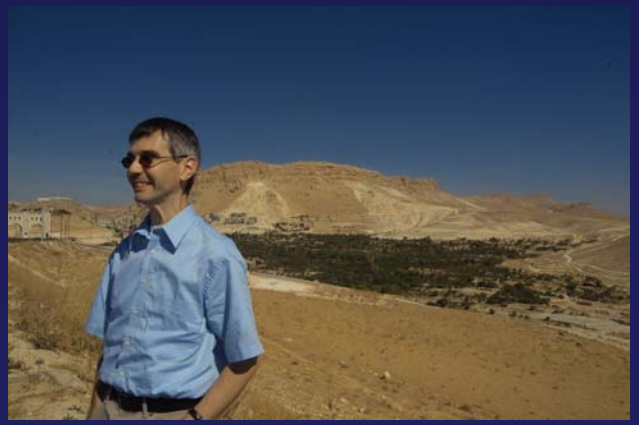

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