

Regulation (EC) n 1924/2006

Member states' role

Parma – 1st June 2010

Technical meeting with
stakeholders

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Global organisation

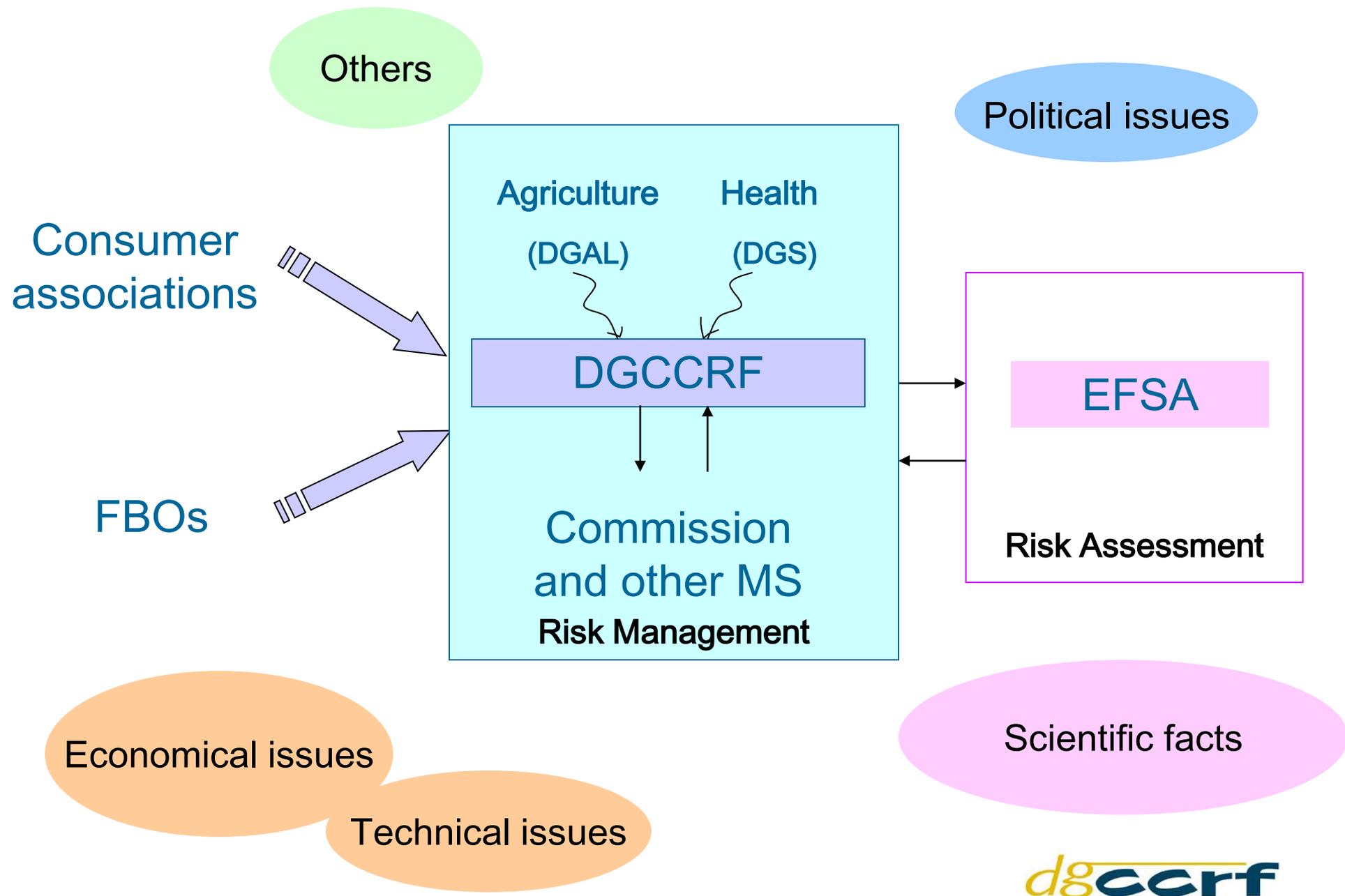
- A national authority in each country is responsible for the implementation of the regulation (EC) n 1924/2006
- Representatives of the 27 MS participate in the **WG on nutrition and health claims** organised in Brussels each month
- Representatives of the 27 MS vote the texts in the **SCFCAH**

Our objectives

- Provide a high level of protection to the consumers (recitals 1 and 9, art1, NHCR)
- Ensure a fair competition between FBOs across Europe (recital 36 and art1, NHCR) : *ensure the effective functioning of the internal market as regards nutrition and health claims*
- Ensure a proper development of the food sector, taking into account its goals and constraints

In France

- The General Directorate for Competition Policy, Consumer affairs and Fraud control (DGCCRF – Ministry of consumption) is the competent authority on topics related to consumer protection (including Food Information to Consumers - Nutrition Labelling, NHC).
 - Participation in the establishment of the framework regulation
 - Enforcement of the text
 - Duties defined in the text
 - Enforcement regulations
 - Control authority



Others

Political issues

Agriculture (DGAL) Health (DGS)

DGCCRF

EFSA

Risk Assessment

Commission and other MS Risk Management

Consumer associations

FBOs

Economical issues

Technical issues

Scientific facts

Art 13.1 claims : the Union list

Tea / Concentration

Iodin /Skin

Vitamin C / Energy metabolism

Magnesium / Nervous system

Calcium / Bones

DHA / Brain

Bilberry / vision

Chocolate / Antioxydant

Beta-glucans/cholesterol

Copper / Immune system

Establishing the list of claims to be evaluated

- **MS are responsible** for those claims
 - Compilation of claims at national level in cooperation with stakeholders
 - Check of their admissibility
- The consolidated list is the synthesis of all claims submitted by MS

Clarification process

- MS were responsible for submitting **additional pertinent information** to allow the assessment of the claim
- In France : consultation of **stakeholders** to provide us with further details

Establishing the Union list

1. Establishment of the national lists
Compilation in all MS
Rejection of non-compliant claims

2. Commission's Compilation
Grouping the similar claims
= About 4200 nutrient/HR claims

3. Transfer to EFSA
Screening
Re-arrangement

← Stakeholders' input

Updated consolidated list on
EFSA's website

Establishing the first list of authorised art.13.1 claims

The importance of the scientific evaluation

- EFSA's opinions are central to our decisions as the scientific substantiation needs to be the main criteria to take into account (recital 17, NHCR).

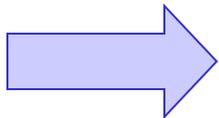
But a positive opinion does not account for an authorisation, and a negative opinion doesn't mean that a claim will be rejected

- MS and CE make sure that all claims are compliant with the regulation...
 - Wording : will to stay as close as possible from the scientific wording, but taking into account the consumer understanding (art 5.2)
 - ... and that their conditions of use are scientifically pertinent and operational (implementation + control)
 - The conditions of use take into account several inputs (science, technology, practical considerations, etc.)

Authorised claims : positive list

- Following the adoption in batches of EFSA's opinions, it has been decided to proceed to a successive authorisation of claims to ensure consumers' protection

–The adoption of each list should be on a par with the batches of EFSA's adopted opinions



Each list (wording + conditions of use) will be voted in the SCFCAH

+ 3 months of Parliament's right of inspection (Regulatory Procedure with Scrutiny)

Negatively assessed claims

- Some of them will be rejected
 - They will be included in the register
 - Pending decision on the transitional measures
- For some others, further assessment is required
 - Ongoing discussions on a way to allow a completion of the dossiers

Next steps

- Adoption of the 1st list in the SCFCAH
 - This list will only deal with claims from the first batch of adopted claims from EFSA.
- Adoption of the following lists (2, 3 and 4)

Art. 13.5 and art.14 authorisation
procedure :
where do MS intervene?

Duties defined in the NHCR and REG (EC) n 353/2008

- Acknowledge receipt of the application within 14 days
- Transfer a **valid** application to EFSA
 - Legal check : complies with the regulations?
 - REG (EC) n 1924/2006
 - REG (EC) n 353/2008
 - Therapeutic claims/ identification of a risk factor
 - Borderline claims with the PARNUT regulation
 - Etc.
 - Completeness check + format check
 - EFSA's Guidance from July 2007

Example of points that are checked

- Only one health relationship / 1 claim?
- Compliant with art.3, 5,10 and 12?
- Scope : therapeutic? Risk factor identified? Target population identified?
- Proprietary/Confidential data : arguments + identified in the application?
- All references provided?
- Does the application follow the format advised by EFSA (5 parts, appendix A, B, C)

All this is made in constant dialogue with the applicant

Transfer of the application to EFSA

- No applications are sent until they comply with the regulatory requirements
- MS remain available during the evaluation procedure to exchange with EFSA and the applicant

Authorisation

- Scope issues might be discussed in the WG on nutrition and health claim
- After an opinion is published by EFSA, all MS and the EC are involved in the authorisation procedure :
 - Work on wording + conditions of use
 - Consultation / Vote in SCFCAH

More general implementation issues

- MS and CE work on interpretation issues of the regulation
 - Specific articles (eg : art.21)
 - Specific claims (eg : source of omega 6)
- MS and CE discuss about borderline issues (eg : therapeutic vs art.14)
- MS and CE work on the articulation between the NHCR and other specific directives (art. 1.5 : PARNUTS, Natural Mineral Waters, etc.)

Conclusion

- MS are at the interface between consumers, FBOs and the european institutions
- Need to conciliate the protection of consumers with the establishment of proportionate rules to be applied by the FBOs
- During the whole process, there is a constant dialogue with stakeholders
- Monthly WG in Brussels allow a harmonized approach in the implementation and the control of the NHCR

Thank you for your attention