Regulation (EC) n°1924/2006
Member states' role

Parma – 1rst June 2010

Technical meeting with stakeholders

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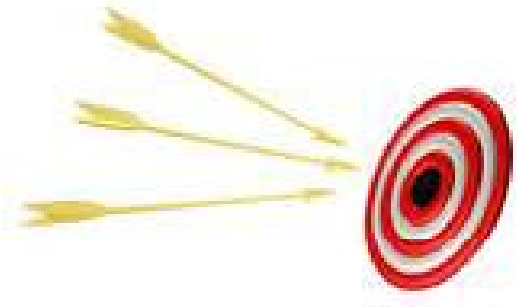
Global organisation

- 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

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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

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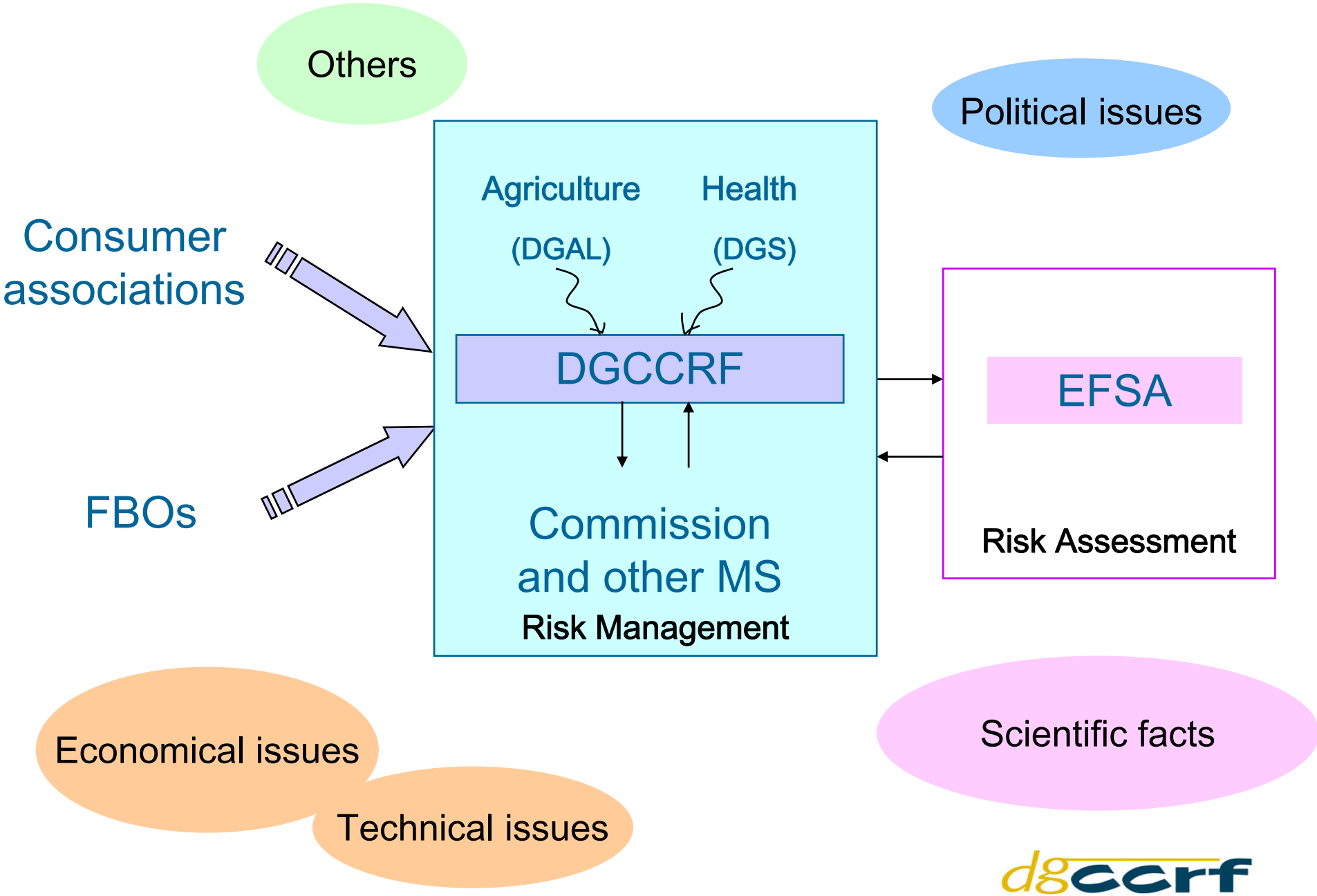
Others
Political issues
Agriculture
Health
(DGAL)
(DGS)
Consumer associations
DGCCRF
EFSA
FBOs
Commission and other MS
Risk Management
Risk Assessment
Economical issues
Technical issues
Scientific facts
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Art 13.1 claims : the Union list

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

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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

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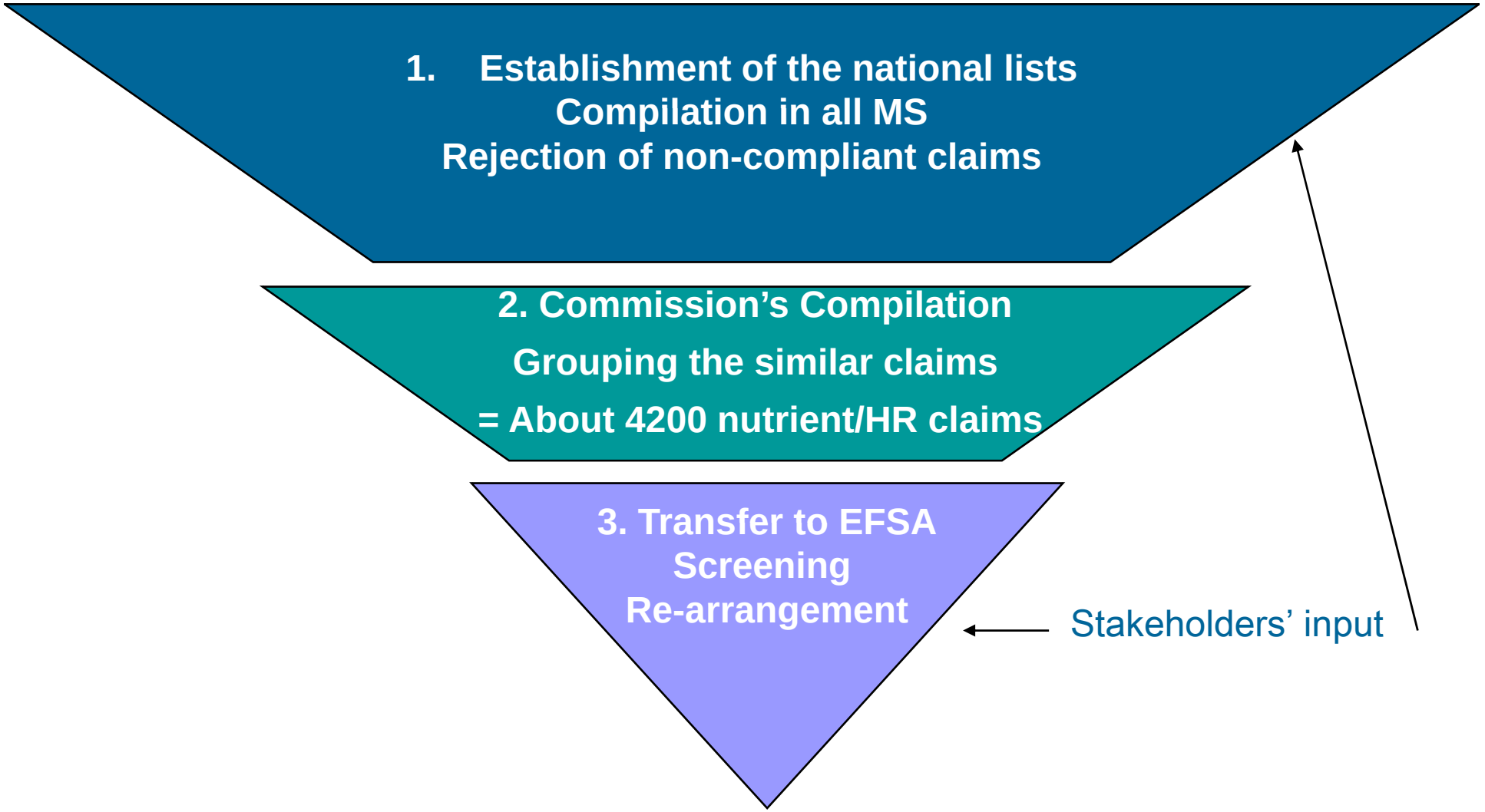
Establishing the Union list



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

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- 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.)

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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)

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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 1rst 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

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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.)

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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

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