ADIPREM
Jornada Técnica 10° Aniversario

Situacion del sector de aditivos y perspectivas

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FEFANA Secretary General

Topics

- Marketing of Feed Regulation
- ID-Feed
- Re-authorisation process
- FAMI-QS developments
- New additive functionalities

Marketing of Feed Regulation

Impact Marketing Feed Regulation

- Feed supplements
- Labelling
- Claims
- Catalogue

Feed supplements

- Highly concentrated products (which largely contain feed additives) not covered by present legislation (« grey zone »)
- E.g. Boluses, drenches, pastes, top dressing, water administration
- Products needed by farmers and thus offered by industry
- + existence / need unanimously recognised
- - regulatory status

Feed Supplements

- Complementary feed Article 8 § 1 (100 times limit – or less …)
- PARTICULAR NUTRITIONAL PURPOSES – Articles 8 § 2 and 10

- TRANSITION PERIOD for existing products already legally placed on the market

Feed Supplements

PARTICULAR NUTRITIONAL PURPOSES approach:

- List of particular nutritional purposes (Directives 93/74 + 2008/38)
- New purposes will need to be established → preparation of application dossiers (Art 10)
- Evaluation / authorisation will be done on claims (not product by product)

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Labelling

- **New labelling regime for feed:**

Labelling": attribution of any words, particulars, trade marks, brand name, pictorial matter or symbol to a feed by placing this information on any medium like packaging, container, notice, label, document, ring, collar or the internet referring to or accompanying such feed, including for advertising purposes;

→**not only what it is printed on the package**

→FEFANA Code of Practice for feed additives and premixtures

Labelling

- Article 16 1831/2003: practical implementation problems for industry and competent authorities.
- FEFANA Code of Practice for feed additives and premixtures + FEFAC
- Article 29 Marketing of Feed :
  - Amends Article 16 of Regulation 1831/2003
  - limits some information on premixtures
  - ALL carriers to be declared
- No flexibility and extension of labelling concept that we have developed
- Unharmonised labelling regime

Labelling

- Adapt Annex IV - Permitted Tolerances

→ FEFANA input

- Commission Impact assessment:
  - revision of the feed additives labelling rules
  - introduce a code of good labelling practice for feed additives

→ FEFANA Code of Practice for labelling

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Claims

- **No claims authorised so far:**

  (exception: dietetic feed)

- **C**ompound feed and feed material - may draw particular attention to the presence of a substance in the feed, to a nutritional characteristic or to a specific function

- Objective, verifiable by the competent authorities and understandable by the user of the feed

→ effects reserved to feed additives or veterinary drugs should be excluded from feed material claims

Claims

- **Substantiation upon request by control authorities:**

-publicly available evidence or throughly documented company research

-substantiation available at the time the feed is placed on the market

-doubts regarding the substantiation: issue could be submitted to the Commission

→ No Commission guidelines / Code for good labelling practice

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Community catalogue of feed materials

(Articles 24, 26)

- **Aim: improve labelling of feed materials and compound feed**
- **Non-exhaustive → no positive list**
- **Voluntary use**

➢ ***(attention: other concept than that of some national lists, e.g. DE, NL)***

Community catalogue of feed materials

Impact on feed additives??

- **YES:**

- ***Carriers of preparation***
- ***Carriers of premixtures***
- ***Co- products fermentation processes***
- ***Complementary feed***
- ***Dietetic feed***

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Community catalogue of feed materials

Characteristics of this list

- **Voluntary use by feed business operators**
  - ***May still use products not in the list***
  - ***But comply with provisions IF business operators decide to apply the catalogue AND the product is listed***
- **Input to the list will come from industry**
- **First placer on the market: shall immediately notify**
- **Link between catalogue and notification ?**

Community catalogue of feed materials

Points not yet explored:

- Level of details of future listed products
  - *Specifications…*
- Operators need to look at Catalogue AND at Directive 2002/32 at the same time
- Identification / correct classification of products is necessary (Commission guidelines)
  → ID-Feed

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ID - Feed

- Classification tool for all individual and mixed feed
- On-line version publicly available
- Article 7 Marketing Feed (guideline distinction feed additive / feed material, etc.)

Feed Additives Re-authorisation process

Context

- Article 10 Feed Additives authorisation 1831/2003
- Most FA must be (re)- authorised under 1831/2003
- by 7 November 2010
- Only successful ones stay on market
- 4 steps:
  - Notification November 2004
  - Entry Register November 2005
  - Application November 2010
  - Authorisation 10 years …

Set up and organisation

- Dossier preparation

- Based on EC guidelines 429/2008 and FEFANA guidance
- Support from EFSA guidance
- Consistency within and between FEFANA consortia
- Concrete / pragmatic way to establish new assessment procedure

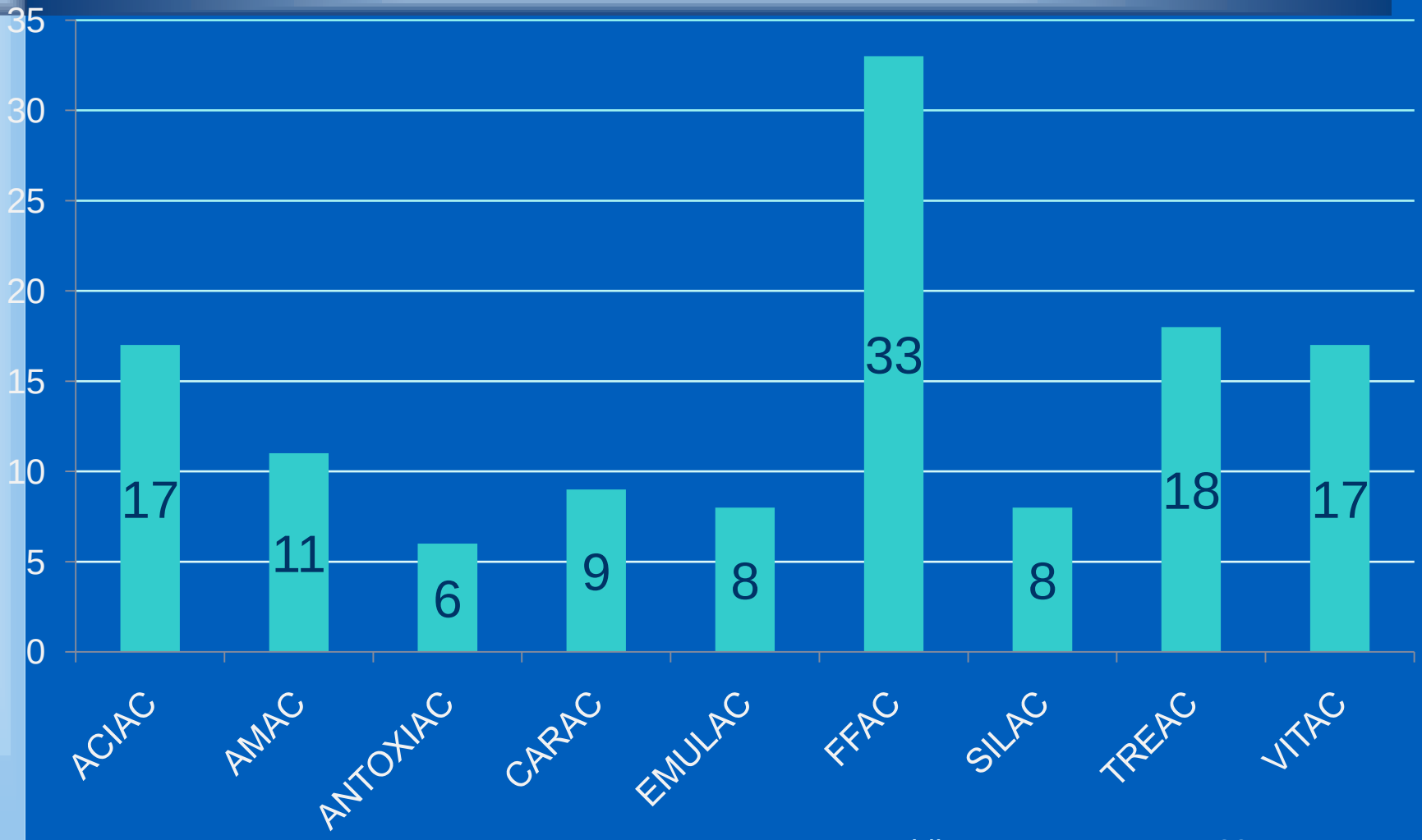
Re-authorisation Consortia

FFAC	flavourings	29.06.2007
VITAC	vitamins	29.06.2007
AMAC	amino acids	25.07.2007
CARAC	carotenoids	31.08.2007
TREAC	trace elements	16.11.2007
SILAC	silage additives	19.02.2008
ACIAC	organic acids (+ silage)	21.02.2008
EMULAC	emulsifiers +	03.07.2008
ANTOXIAC	antioxidants	25.09.2008

What's next ?

- UREAC
  - Urea and its derivatives
- Binders / anti-cacking agents (MINAC)
  - Managed by IMA with support of FEFANA
- Synthetic colorants, synthetic binders, orphans …???

How many companies ?



Consortia and the web

Back to FEFANA Web Site

Feed Additives Authorisation Consortia – EEIG-European Economic Interest Groupings

aciac amac carac emulac ffac silac treac vitac

FEFANA Consortia News | Q&A | Consortium Acids (ACIAC) | Consortium Amino Acids (AMAC) | Consortium Carotenoids (CARAC) | Consortium Emulsifiers (EMULAC) | Consortium Feed Flavourings (FFAC) | Consortium Silage Additives (SILAC) | Consortium Trace Elements (TREAC) | Consortium Vitamins (VITAC)

Reg. (EC) No 1831/2003 rules the access to the EU market for feed additives: this is a system of pre-market approval applying to all additives on the market. It includes provisions for the feed additives previously authorised, allowing them to stay on the market provided a sequence of conditions are successfully fulfilled (Article 10 of the Regulation):

- notification of placing on the market of the authorised additives by the parties concerned (deadline November 2004);
- check of the validity of the submission by EFSA (European Food Safety Authority);
- inclusion of the additives successfully notified in the EU Register of feed additives by the EC (EU reference list of authorised additives initially established in November 2005 and regularly updated since then);
- tabling of a complete authorisation dossier to EFSA and EC by November 2010 in order to obtain a regular 10-year authorisation;
- authorisation under Reg. (EC) No 1831/2003 for 10 years.

According to the sequence of events foreseen by the Regulation, the additives that were successfully entered in the EU Register in 2004 must now undergo a complete authorisation process in order to stay on the EU market.

In order to launch this authorisation procedure, application dossiers must be provided to the authorities by 7 November 2010 at the latest.

These dossiers must be prepared according to a Guideline Regulation that the European Commission is about to finalise. For several years, FEFANA has been actively involved with the EC and EFSA in the preparation of this pivotal document. It recommends and supports its members to launch practical work immediately in order to meet the 2010 deadline.

While the authorisation of feed additives subject to a holder-specific authorisation (zootechnical additives and GMO-derived ones) is generally well under control by the companies producing or placing them on the market, the situation of all additives subject to non-holder-specific authorisation (sometimes incorrectly referred to as "generic") is more delicate. The authorisation is indeed a shared responsibility of all the operators that produce, use or place a certain additive on the market. All operators aware of these developments realised that it would be very inappropriate to wait for somebody else to care alone about the authorisation, not only because it would be unfair to their competitors, but also because the specifications, purity criteria and manufacturing processes are to be part of the evaluation and final authorisation of each additive. Those who do not take part might well discover at the end of the process that their additive has lost its market authorisation.

In order to help its membership, and industry in general, to establish the necessary coordination, FEFANA is progressively setting up authorisation consortia. They are established in the form of European Economic Interest Groupings (EEIGs), legally separate but closely related to FEFANA. Each EEIG is focusing on a specific group of feed additives, according to the need and priorities identified by FEFANA Members. The fact that a grouping is established does not mean that it will automatically take care of all the additives pertaining to it. Each grouping has defined objective criteria in order to bring (or not) specific additive under the scope of work of the grouping. The established EEIGs are open to non-FEFANA members.

Close cooperation is being established with EFSA in order to streamline the process as much as possible. Beside the access to the vast know-how established within FEFANA over the years, the reduction of individual burden, the sharing of cost, the legal framework it provides for companies to cooperate, the close relationship with EFSA can be seen as an important added value for these groupings. It is indeed of paramount importance for any applicant to avoid investing time and efforts leading to dead ends.

Information and application forms available from FEFANA Secretariat:

120 Avenue Louise - Box 13
1050 Brussels
Belgium
Tel.: +32 (0)2 639.66.60

http://www.fefana.org/EEIG/Authorisation%20Consortia.htm

More information: eeig.additives@fefana.org

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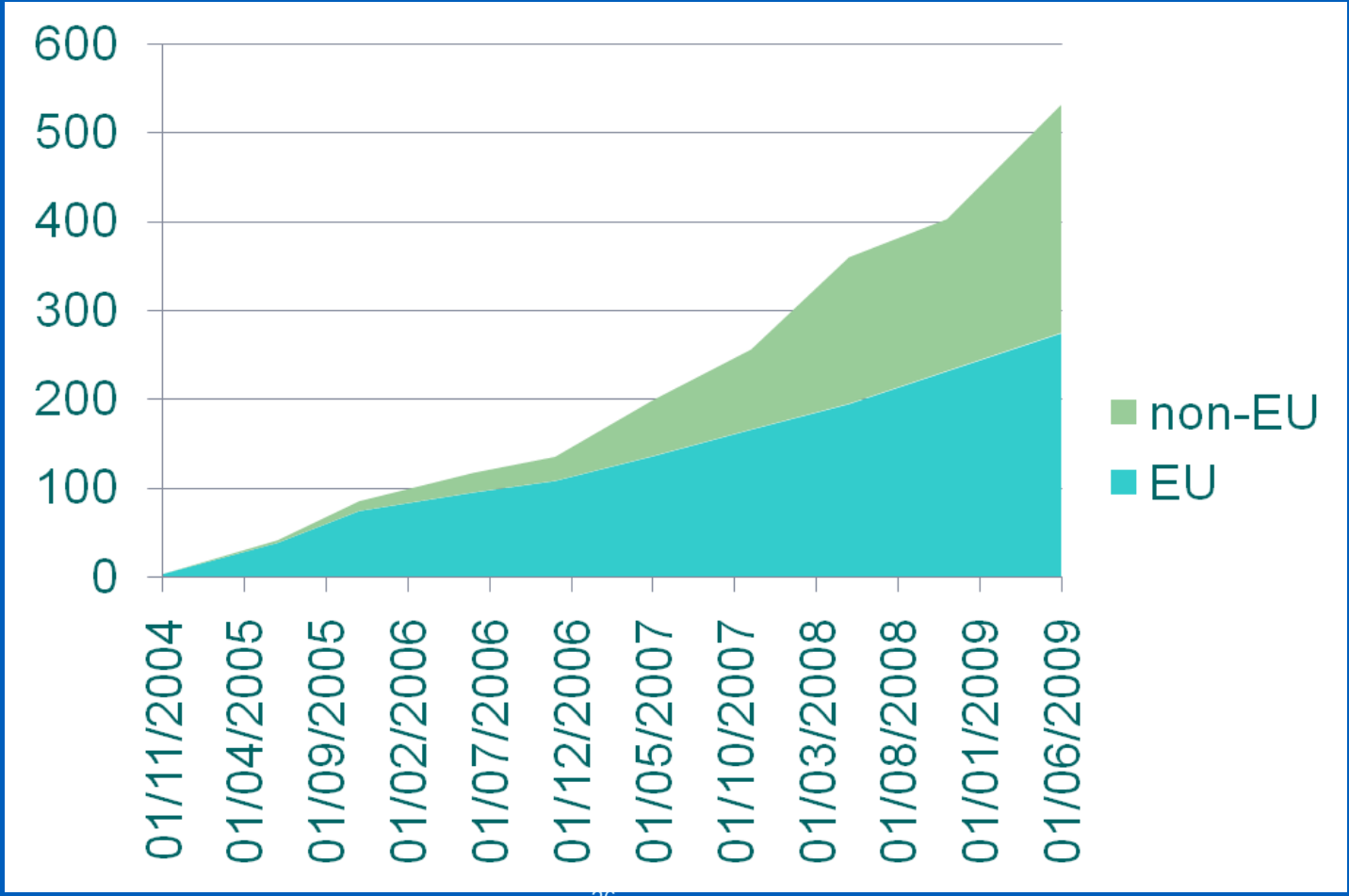

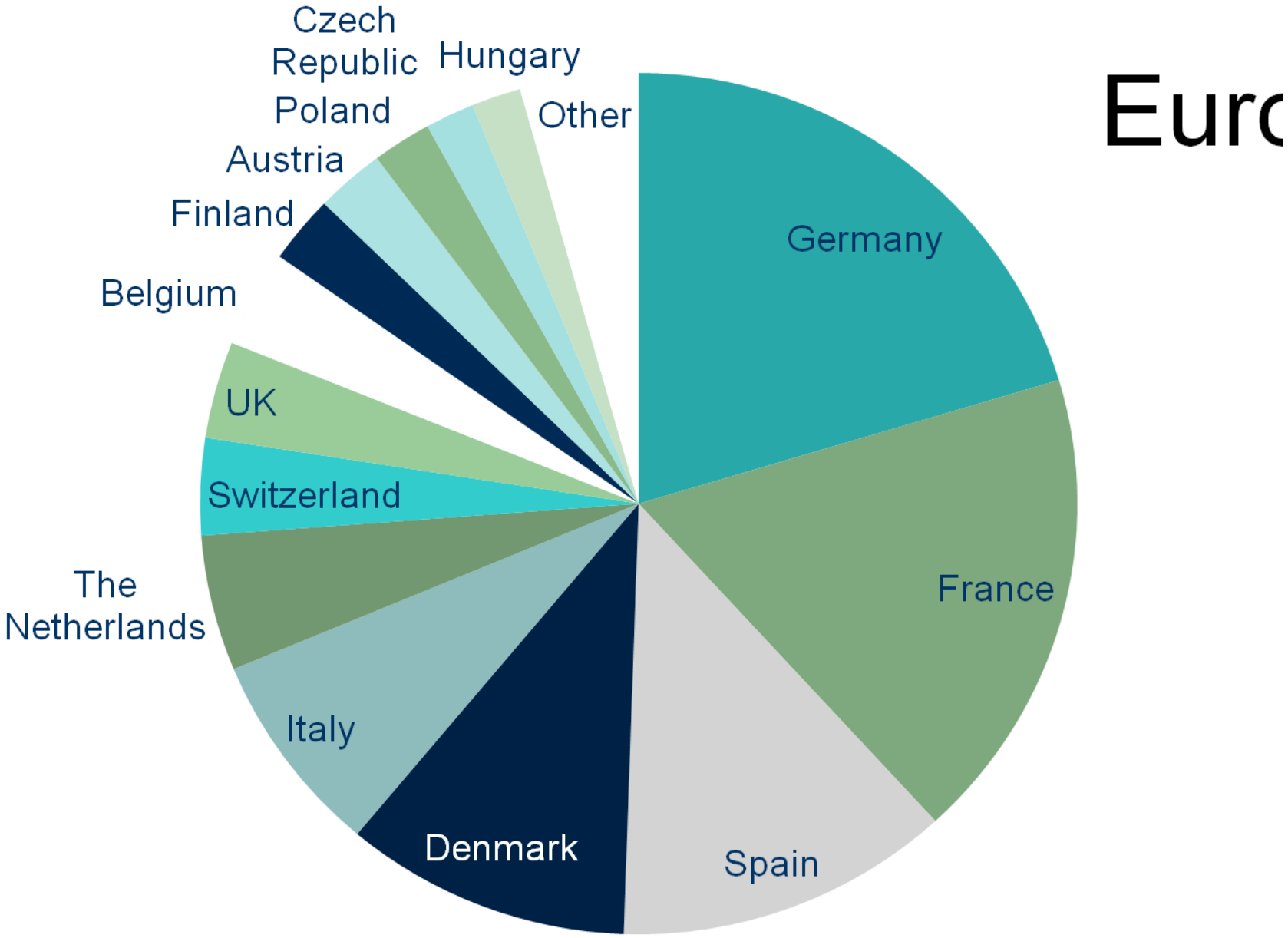
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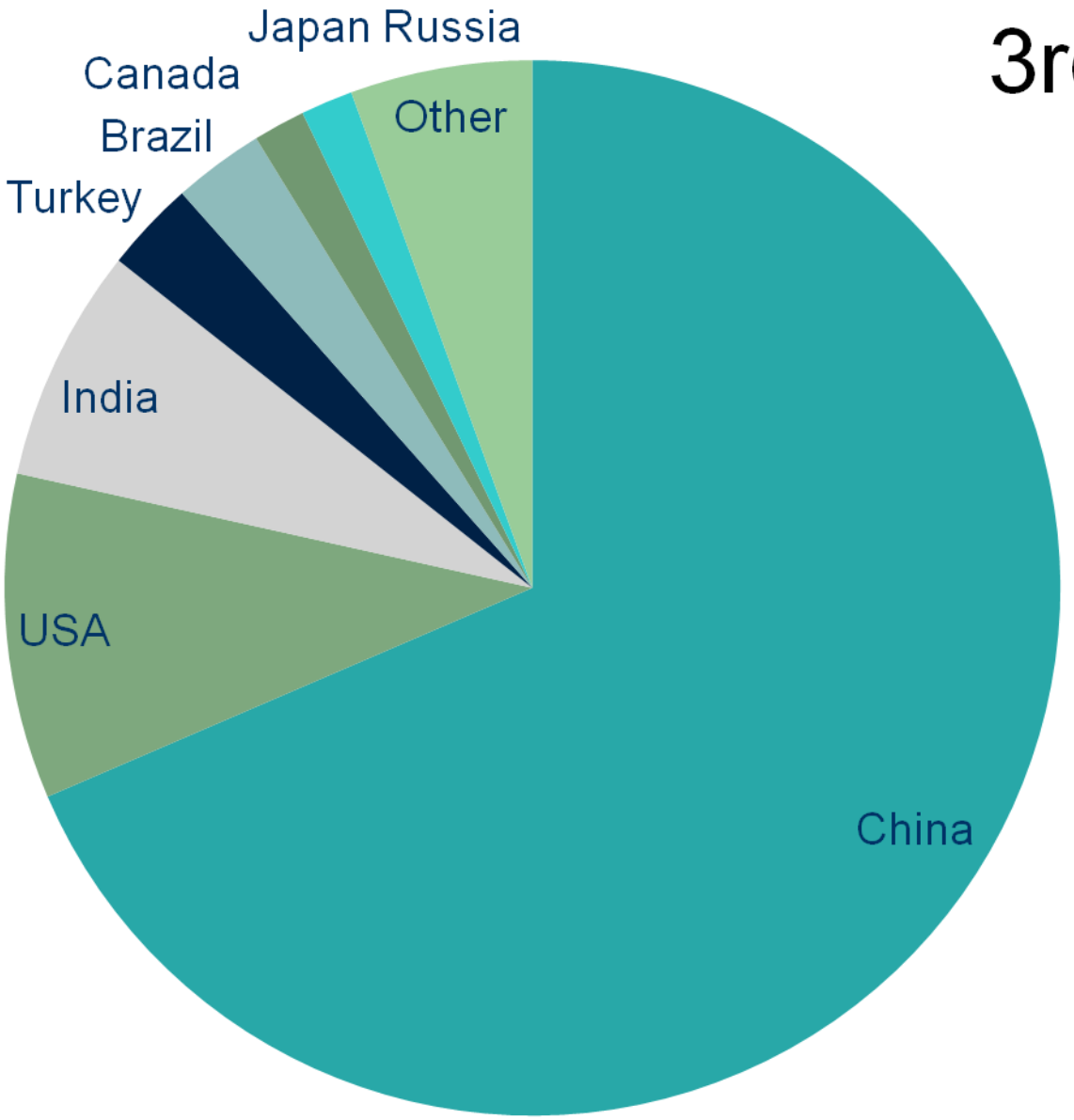

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Sindiracoes (Brazil) and AFIA (USA)

- 27 January 2009 (2nd Feed Regulators Meeting Atlanta, Georgia)
- **Memorandum of Co-operation** signed between:
- **FAMI-QS**
- Sindicato Nacional da Industria de Alimentação Animal **(Sindiracões)**
- American Feed Industry Association **(AFIA)**

Brazil and US

- Strong co-operation and communication
- Local auditors to inspect US or Brazilian operators for FHR compliance
- Train professionals from US/Brazilian CBs to provide FAMI-QS audits
- Facilitates trade between these countries and EU
- Facilitates trade between EU and these countries

FAMI-QS Upgrades

- Upgrade Code
  - Source assurance
  - Crisis management
  - Subcontractor approval
- Upgrade certification rules
  - Rules for certification bodies
  - Rules for operators
  - Audit monitoring

New Functionalities Feed Additives

New functionalities - Feed additives

- “Substances for reduction of contamination of feed by mycotoxins: substances that can suppress or reduce the absorption, promote the excretion of mycotoxins or modify their mode of action”
- Functional group 1 m (technological additive)

- Regulation 386/2009 - Excellent move
- Risk Manager responsibility
- Adaptation guideline 429/2008 (limited) by Risk Manager – Technological additives -

Technological Additives

- Technological additives
  - improve or stabilize the characteristics of feed
  - have generally no direct biological effect on animal production
- The primary action of a “mycotoxin adsorbent/denaturant” is to act on the feed by inactivating the mycotoxins present.
- Animal performance would be a secondary consequence of the inactivation effect.

Efficacy Assessment

- *in vitro* assays
- Acting below mycotoxins maximum limits defined by Directive 2002/32 (AFB1) + Recommendation 2006/576 (DON, ZEA, OTA, FB1+FB2, T2, HT2).
- No hiding effect of mycotoxins in feed. Present mycotoxins remain quantitatively detectable (→ NO cleaning of adulterated feed and feed materials)
- Nutritional values are not compromised (energy level, protein levels, vitamins, etc.)
- 2 in vitro methods developed (adsorbants / denaturants)

New Functional group 1m

- Totally fits in the concept of prevention
- A tool to further improve:
  - quality assurance
  - safety of feed and food
- Not capable of cleaning alleviated feed materials
- Transparent regulatory environment for substances that reduce the contamination of feed
- Pre-market approval authorisation process

Thank you

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