FoodDrinkEurope Position on GLP studies

FOODDRINK EUROPE

Content of the presentation

- Introduction to GLP
- Importance of GLP for the food industry
- Use of GLP based on the example of novel foods
- Conclusions

FOODDRINK EUROPE

GLP what is it?

- Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed
- GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments

FOODDRINK EUROPE

Introduction to GLP

- Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances,
- Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP),
  - The Directive requires that the OECD Revised Guides for Compliance Monitoring Procedures for GLP and the OECD Guidance for the Conduct of Test Facility Inspections and Study Audits must be followed during laboratory inspections and study audits.,
- 89/569/EEC Council Decision of 28 July 1989 on the acceptance by the European Economic Community of an OECD decision / recommendation on compliance with principles of good laboratory practice.

FOODDRINK EUROPE

Product Oriented Directives' referring to GLP obligations

- Chemical substances; Regulation (EC) N 1907/2006
- Medicinal products
- Veterinary Medicinal Products
- Cosmetics
- Feedingstuffs (additives)
- Foodstuffs (additives, flavourings)
- **Novel Foods and novel food ingredients; Regulation (EC) No 258/97**
- Claims
- Pesticides
- Biocides
- Detergents
- EC Ecolabel; Commission Decision 2005/344/EC

FOODDRINK EUROPE

GLP studies requirements

- Adequate and permanent documentation of everything involved in an experimental test:
  - Staff qualifications,
    Valid study design,
  - Standard operating procedures (SOPs),
  - Training,
  - Performance,
  - Formulation,
  - Statistical analyses, and
  - Retention of summary/individual data

FOODDRINK EUROPE

Product oriented legislation – Novel Food and Novel Food Ingredients (1)

- COMMISSION RECOMMENDATION of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council

Product oriented legislation – Novel Food and Novel Food Ingredients (2)

- To protect public health, it is necessary that novel foods and novel food ingredients are subject to a single safety assessment through a Community procedure before they are placed on the market within the Community;
- Data submitted should be based on studies carried out according to the principles of Good Laboratory Practice (GLP)

FOODDRINK EUROPE

Product oriented legislation – Novel Food and Novel Food Ingredients (3) - Categories of Novel Foods and Novel ingredients

- Foods and food ingredients with a new or intentionally modified primary molecular structure;
- Foods and food ingredients consisting of or isolated from microorganisms, fungi or algae;
- Foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating and breeding practices and which have a history of safe food use;
- Foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or the level of undesirable substances.

FOODDRINK EUROPE

Product oriented legislation – Novel Food and Novel Food Ingredients (4) Key Issues for Assessment

- Substantial equivalence
- Compositional analysis
- Intake
- Nutritional considerations affecting toxicological testing in animals
- Toxicological requirements
- Allergenic potential
- Microorganisms used in food
- Implications of NF to human nutrition

FOODDRINK EUROPE

Product oriented legislation – Novel Food and Novel Food Ingredients (5) – Toxicological Considerations

- Consideration of the possible toxicity of the analytically identified individual chemical components,
- Toxicity studies in vitro and in vivo including mutagenicity studies, reproduction and teratogenicity studies as well as long term feeding studies, following a tiered approach on a case-by-case basis,
- Studies on potential allergenicity.

FOODDRINK EUROPE

Conclusions

- The safety for the consumers is paramount
- Confidence in the study's design, performance and its results is key
  - Public agencies have access to the GLP records, subsequently the study can be reconstructed if so decided
- Indeed the recognition of the use of GLP studies is important information, reassuring the quality of the applicant studies

FOODDRINK EUROPE

To find more information about FoodDrinkEurope

www.fooddrinkeurope.eu

Access to news, positions and publications

FOODDRINK EUROPE