Outline

- New requirements under Food Information Regulation (1169/2011)
- Specific clean label issues:
  - enzyme information
  - use of ‘natural’
- Health claims
- New distance selling requirements
- The new enforcement environment
NEW REQUIREMENTS UNDER THE FOOD INFORMATION REGULATION
Countdown to New Food Information Requirements

- Food Information Regulation 1169/2011
  - ‘foods intended for the final consumer’ and mass caterers
  - any form of communication (not just label) - online etc.

- Minimum font size for ‘mandatory particulars’ (allowance for small packs)
  - name, ingredients, allergens, quantity of certain ingredients, net quantity, minimum durability (or ‘use by’) data, special storage conditions, name and business name of FBO, country or place of provenance where required, instructions for use, nutritional declaration
  - combined with increased mandatory information, multiple languages
  - less label space for product positioning (voluntary) information
    - ‘voluntary food information shall not be displayed to the detriment of the space available for mandatory food information’

- Mandatory nutritional declaration
Countdown to New Food Information Requirements

- Extension of mandatory country of origin
- Allergens rules strengthened
- Distance Selling (online) of foods
- Additional information for certain ingredients
Liability for Food Information Compliance

- **Liability**
  - ‘FBO responsible for the food information’
    - EU-based operator under whose name product marketed; or
    - if no such operator, importer
    - online trading: website owner (Commission Q&A 31.1.13)
  - in addition, all FBOs to ensure compliance with food information requirements 'relevant to their activities' (Article 8(5))

- **Case-315/05 (Lidl Italia):**
  - MS national laws *can* impose liability on distributors for non-compliant product labelling (of manufacturer)
    - Court did not appear to address Lidl’s defence argument that: ‘The distributor cannot know whether or not the label affixed to the packaging by the producer…’
    - Advocate-General’s more nuanced approach not referred to in judgment: only if distributor ‘in a position to verify that the particulars on the label of the product are substantively accurate’ (defence in any enforcement action?)

- **Importance of contractual indemnities from upstream supplier**
Deadlines and Transitioning to New Regime

- **Transitional periods**
  - most provisions apply from 13 December 2014
    - composition and labelling criteria for minced meat already applies
    - mandatory nutrition declaration from 13 December 2016 (new presentation from December 2014 where claim or voluntary nutritional declaration)

- **Label redesign timing?**
  - can transition to new label regime now, provided no breach of existing legislation (Directive 2000/13) (Commission Q&A (31.3.2013))
    - for instance, under Directive 2000/13/EC, the 'best before' date must be in the same field of vision with the name under which the product is sold…
  - ‘stroke of midnight’ replacement?
  - technical breach of law today
    - enforcement not in public interest
FIR Framework (I) – Further Commission Action

- FIR a framework regulation to significant extent
- Long list of implementing legislation and Commission reports (potential legislation) to come:
  - alternative expression of mandatory particulars by pictograms and symbols
  - expression of mandatory particulars other than on package and label
  - nutritional information on alcoholic drinks
  - amend allergens list
  - add or remove nutritional declaration particulars
  - expression and presentation of nutritional declaration
  - report on transfats, leading to possible restrictions
  - conditions for use of voluntary information for certain foods
FIR Framework (II) – Additional National Measures

- National measures:
  - on matters specifically harmonised by Regulation prohibited (except if specifically authorised under Union law)
  - on matters not specifically harmonised by Regulation permitted, provided not trade barriers within the EU

- Specific provision for national measures in certain areas including measures on:
  - milk in reusable glass bottles
  - pending any Union provisions in those areas:
    • maintenance of existing measures re alternative expression of net quantities of specified foods and ingredients listing for low alcoholic drinks; and
    • adoption of new measures re voluntary indication for reference intakes for specific reference groups
  - additional mandatory particulars
Nutrition Declaration: Transitional Periods

- New nutrition declaration presentation rules bite:
  - from 13 December 2014:
    - for foods already subject to nutrition labelling: health or nutrition claims (Regulation 1924/2006) or to which vitamins and minerals added (Regulation 1925/2006); or
    - where nutrition declaration provided on a voluntary basis
  - from 13 December 2016 for all other foods, except:
    - those specifically exempted in Annex V
    - more than 1,2% alcoholic drinks
    - those under own separate nutrition labelling schemes (food supplements, mineral water, PARNUTS)

- To facilitate transition to new requirements, Regulation expressly permits labelling in accordance with new rules before 13 December 2014: all or nothing, canno ‘cherrypick’ (Commission Q&A 31.1.2013)
Nutrition Declaration: the New Regime

- Changes to content and presentation

- Content:
  - mandatory particulars: energy value and amounts of fat, saturates, carbohydrate, sugars, protein and salt
  - optional particulars:
    - one or more of mono-unsaturates, polyunsaturates, polyols, starch, fibre and/or certain vitamins where present in ‘significant amounts’
    - salt content due exclusively to naturally occurring sodium
    - repeating of certain mandatory information elsewhere on label

- Voluntary nutrition declaration must adhere to same rules, except:
  - energy value only for more than 1,2% alcoholic drinks
  - energy value only, or together with amounts of fat, saturates, sugars and salt only for non-prepacked foods
Nutrition Declaration: Expression (per what?)

- Specific rules on calculation of energy values and nutrient amounts
- Mandatory measurement units for expression of energy value and specified nutrients
  - where appropriate, can state ‘Contains negligible amounts of…’ energy/mandatory nutrients near declaration
  - Guideline Daily Amount (GDA) not permitted
- Energy value or nutrient amount expressed how/of what?
  - mandatory:
    - per 100g or 100ml
    - plus % of specified reference intakes per 100g or per 100ml for permitted vitamins and minerals
  - optional (in addition to mandatory above):
    - plus % of specified reference intakes per 100g or per 100 ml for energy value and specified nutrient amounts; and
    - per portion and/or per consumption unit (if portion and number of portions defined)
  - more limited requirements permitted for mandatory nutrition information repeated elsewhere on label and non-prepacked foods
Nutrition Declaration: Presentation

- Mandatory and optional particulars in same field of vision and in following **new** order (not all may be applicable):
  - energy
  - fat
    - of which
      - saturates
      - mono-unsaturates
      - polyunsaturates
  - carbohydrate
    - of which
      - sugars
      - polyols
      - starch
  - fibre
  - protein
  - salt
  - vitamins and minerals
Nutrition Declaration: Presentation

- Tabular format with numbers aligned ‘if space permits’
  - otherwise linear format
  - different requirements for repeated mandatory information, more than 1,2% alcoholic drinks and non-prepacked foods

- Different additional (not alternative) types of ‘per what’ expression and layout (graphical forms) permitted if consumer research suggests meaningful and not misleading to consumer
  - Member States may recommend, monitor and/or require notification (with proof of meeting criteria)

- Nutrition Declaration in various formats (EU and US?) prohibited
  - same rules for voluntary information
  - different calculation factors = misleading
Mandatory Particulars

- In addition to ‘standard’ mandatory particulars…

- Additional mandatory particulars, for example:
  - **caffeine**: certain caffeinated beverages with over 150 mg/l caffeine: ‘High caffeine content. Not recommended for children or pregnant or breast feeding women ([ ] mg/100 ml)’ (Annex III)
  - **trans fats**: hydrogenated oils and fats: indicated as ‘fully hydrogenated’ or ‘partly hydrogenated’ (Annex VII)
    - MEP question: will consumer understand?
  - engineered nanomaterial ingredients
    - ‘[ingredient name] (nano)

- National measures permitting additional mandatory particulars, subject to protectionist/trade barrier safeguards:
  - for specific types/categories of food if justified on grounds of health, consumer protection, fraud prevention and industrial and commercial property rights
  - for non pre-packaged foods (in addition to allergens)
  - country of origin where proven link between food qualities
  - dedicated notification and Commission clearance procedure
Country of Origin (I)

- Extension of mandatory country of origin (of last substantial processing) or place of provenance (origin which is not country of origin) of food
  - if omission misleading
  - fresh, chilled and frozen pig, sheep, goat and poultry meat*
  - potential extension to other food categories (Commission report by December)

- State origin/provenance of primary ingredient (or that different) if different from stated origin/provenance of food

* Commission Implementing Regulation 1337/2013: applicable 1st April 2015
  - balance between consumer information and added cost for industry/consumer
  - consumers most interested to know where animal reared
  - ‘Origin: [country]’ only where born, reared and slaughtered in same country
  - otherwise ‘Reared in: [last country where defined minimum rearing period (depending on animal) satisfied]’ or ‘Reared in: several EU MSs and/or several non-EU countries [or specific countries listed]’, plus ‘Slaughtered in: [country]’
Country of Origin (II)

- imported meat can say ‘Reared in: non-EU’
- FBO permitted to add further provenance indication
- complicated!

- Potential extension to other food categories:
  - meat used as an ingredient (Commission report adopted end 2013)
  - other types of meat, milk (including as an ingredient), unprocessed foods, single ingredient products, ingredients constituting more than 50% of food (Commission report due)

- Factors
  - feasibility of providing meaningful COO information to consumers
  - costs and benefits
  - report on meat used as ingredient:
    • consumer reticence to pay additional cost (15-30% of price, passed on to consumer)
    • negative trade impact due to necessary changes in supply chain, but …
    • media pressure
    • highly politicized due to horsemeat scandal – likelihood of legislative proposal?
Allergens

- Applies to: ingredients or processing aids which are allergens, or derived from allergens, and still present, even in altered form

- Scope:
  - importance means no exceptions, despite consequent practical difficulties
    - includes small packs and non-pre packaged foods exempted from ingredient labelling

- Meeting the new requirements:
  - obvious from name of product; or else
  - name of allergen emphasized in ingredients list using typeset (font, bold, different colour); or else
  - where no ingredient listing, state ‘Contains [allergens]’
  - significant liability implications if omitted
    - UK: £5,000 maximum fine limit changed to unlimited maximum (section 85 of the Legal Aid, Sentencing and Punishment of Offenders Act 2012)
  - Commission to legislate on ‘may contain’ labelling
    - voluntary precautionary allergen statements only where real risk assessed/identified?
CLEAN LABEL ISSUES
Enzymes Labelling Exemption – still available?

- **Pre Regulation 1332/2008:**
  - if not used as additive (invertase and lysozyme), then use as a processing aid exempt from labelling (almost all enzymes)
    - except if originate from allergen ingredients (Article 6(10) Directive 2000/13, Article 9(1)(c) of Regulation 1169/2011)

- **Now** enzymes can be a specific ingredient in own right
  - ingredient: ‘Preservative: [Enzyme name]’ if belonging to one of the [functional] categories listed…’

- **Application dossier for Community List must:**
  - demonstrate processing aid (why not ingredient)
    - protect processing aids labelling exemption post Community list
  - ‘function and technological need including a description of the typical processes in which the food enzyme may be applied’
  - ‘the effect of the food enzyme on the final food’ (Article 9(2)(b) and (c)
Natural (I)

- ‘Natural’ not defined in EU food law

- General ‘Misleading to Consumer’ Test
  - labelling/advertising not to ‘mislead purchaser to a material degree...’ as to characteristics: nature, properties, origin or provenance, method of manufacture or production’ (Article 2(1)(a)(i) of Directive 2000/13, Article 7(1) of Regulation 1169/2011, Article 16 of 178/2002)
  - general concept: room for interpretation (and abuse?)
  - open space for enforcement, competitor cease and desist action

- National differences:
  - French: cannot say ‘natural’ if ingredient is always natural (Directive 2000/13, Article 2(1)(a)(iii))
    - spirit contradicted by the Nutrition and Health Claims: ‘Where a food naturally meets the condition(s) laid down in this Annex for the use of a nutritional claim, the term ‘naturally/natural’ may be used as a prefix to the claim.’
Natural (II)

  - ‘means essentially…not the work of man or interfered with by man’
  - ‘fermentation is itself a natural process but subsequent processes may disqualify the final product from the description natural..’
  - ‘non-traditional fermentation processes should not be referred to as natural’

- EU level
  - EU caselaw (C-465/98 Darbo, paras 25 - 29): average consumer will not interpret ‘natural’ literally (presence of residues, impurities in jam)

- Flavourings Regulation 1334/2008: only FIA Regulation dealing specifically:
  - provides for use of term ‘natural flavouring substance’ if (Article 3(2)(c), Article 16(3):
    - correspond to substances naturally present and have been identified in nature
  - suggests ‘natural’ may legally have more subtle meaning than not created by man

- Ingredients made with GMO enzymes?
  - for example, fructose made by GMO glucose-isomerase
  - academic comment/not law – natural if:
    - amino acid sequence of GMO enzyme similar to natural variant
    - effect on ingredient comparable with that of a natural variant
HEALTH CLAIMS
Scope of ‘Health Claim’: Requirement to Specify Health Benefit

- Monsterbacke (German Federal Court of Justice Case I ZR 36/11, order of 5 December 2012)
  - claim ‘as recommended as the daily glass of milk’ on dairy fruit drink
  - ‘health claim’ under Article 2(2)(5) NHCR implied despite no specification of particular health benefit (Senate finding)

- Health claim or statement of fact?
  - ‘lutein is one of the carotenoids found in the macula of the human eye’
  - indication that ‘relationship exists between food [constituent] and health’? (Article 2(5) NHCR) (no ‘increasing, helping, maintaining…’)

- § ENRA guidance (section 1.2.3):
  - ‘However, even though such statements are factually true, their use may mislead consumers to think that intake has a benefit and therefore result in such statements becoming unauthorized health claims.’
DISTANCE SELLING AND FOOD
Distance Selling

- Distance selling (online) of foods under the FIR
  - all mandatory information (except durability date) available upfront pre-purchase

- Directive 2011/83 on Consumer Rights
  - ‘If you own a business that sells stuff then it is something you really need to know about. I doubt there's a retailer in the land who won't be affected by these changes, and for some it will require a major overhaul of their systems, processes and staff training…’ (‘Is UK retail ready for new EU directive?’ The Guardian, January 17 2014)
  - from last June (2014), covers foods sold on web
    - online supermarket sales
    - food supplements
    - non-EU hosted websites covered if target EU market

- Achieving compliance:
  - review web ordering processes, terms and conditions, distribution arrangements:
  - train relevant staff and revise internal policies
New Requirements at a glance

- **Withdrawal from contract:**
  - longer 14 day withdrawal period (including prior to download of digital content),
  - new deadlines for return of goods and reimbursement
  - clarification on who is responsible for associated delivery and return costs,
  - circumstances for partial refunds where goods damaged

- **Transparency of costs and payment obligations:**
  - maximum costs clearly specified
  - express/active agreement from consumer to pay initial and additional costs required to be binding (default ‘pre-ticked’ boxes for additional payments illegal)
  - excessive charges for payment methods (debit/credit cards) and consumer hotlines illegal

- **Delivery of goods and risk:**
  - delivery within 30 days of contract conclusion
  - risk borne by traders until consumer takes possession (unless transport arranged by consumer)
ENFORCEMENT
Enforcement Trends

- Food information increasingly an enforcement priority
- Recent European food fraud scandals
  - horsemeat
  - Methanol-laced vodka
- New Commission regulation on official controls/enforcement:
  - improved cross border enforcement through integrated information management system
  - mandatory ‘naming and shaming’ provisions
  - increased unannounced inspections
- Private enforcement: competitors and consumer associations ‘cease and desist’ letters and potential injunctions
- Pressure from self-regulatory organisations like UK ASA (jurisdiction now extended to websites) (cases/decisions published)
- Busines interruption and reputational damage
Take Home Messages

▪ New food information regime from 13 December 2014:
  – easily discernible new mandatory obligations

▪ Liability implications:
  – for example, re allergens
  – upstream compliance guarantees and indemnities?

▪ FIR a framework:
  – further obligations going forward – watch this space!

▪ Survival of clean label:
  – enzymes functional category to be stated
  – use of ‘natural’:
    • inconsistent law and guidance in different EU countries
    • EU position helpful

▪ Health Claims:
  – recent case law a step too far re scope?

▪ Distance sales:
  – are T&Cs and presentation of website compliant?
Steptoe & Johnson Food Practice

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