Lovells

Newsletter
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Food, feed and drink quarterly update

In this issue

This newsletter is Lovells' Food, Feed and Drink team's quarterly update of a number of regulatory developments in EU and Member State law and policy that are of interest to the Food, Feed and Drink sectors. This newsletter is not intended to be an exhaustive commentary on all developments, and we would welcome comments or suggestions as to areas where we could expand or focus our review in the future.

ABOUT LOVELLS

Lovells is an international law firm with 26 offices located in 19 countries. In Europe, Lovells offers both domestic and cross-border business law expertise in 11 jurisdictions, with European Community law expertise in the form of a Brussels office.

Lovells' pan-European Regulatory Practice combines the firm's extensive experience in dealing with regulatory issues across Europe. The broad scope of our expertise, together with our years of experience in heavily regulated market sectors, allows our team to help to influence the shape of a new piece of legislation, ensure compliance with legal requirements and help deal with issues following a challenge from a regulatory authority. Our regulatory support helps our clients to achieve competitive advantage and minimise regulatory risks. It allows businesses to achieve maximum benefit from both the current legislation and future developments whilst providing a safety net to prevent or reduce the negative impact of future regulatory changes.

We have an experienced international regulatory team of lawyers and public policy practitioners based in London, Brussels and other international offices.

Food, feed and drink quarterly update

New EU food and feed hygiene legislation finalised

SUMMARY

The consolidation and simplification of food and feed hygiene legislation was a key priority of the European Commission's White Paper on Food Safety published in January 2000. In July 2000 the European Commission ("the Commission") put forward a "food hygiene package" consisting of five proposals, the aim of which was to "merge, harmonise and simplify" the law on food hygiene. A parallel Regulation on feed hygiene was proposed by the Commission in April 2003. Finally, in order to facilitate the enforcement of the new hygiene rules by EU and Member State competent authorities, the Commission also proposed a Regulation on Official Food and Feed Controls in February 2003.

All these measures have now been agreed by the EU thereby paving the way for a single, transparent hygiene policy, applicable to all food and feed operators.

The new legislation will be applicable from 1 January 2006, although the application of certain provisions is in some cases delayed as specified to allow longer for compliance with the new requirements.

FOOD HYGIENE PACKAGE

The aim of the food hygiene package is to streamline and consolidate the existing legislation, and create a single, transparent hygiene policy applicable to all food operators. The new food hygiene legislation will repeal and replace the existing 17 food hygiene Directives, 16 of which are commodity specific.

The package comprises the following measures:

- a general hygiene Regulation with rules applicable to all food sectors;
- a Regulation with specific rules for products of animal origin;
- a Regulation for official controls on products of animal origin intended for human consumption, which sets out rules for official controls of fresh meat, live bivalve molluscs and milk and milk products;
- a Regulation on animal health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption;
- a Directive repealing and amending existing legislation.

Main points of the new Food Hygiene Regulations

Responsibility - Under the new Regulations, food producers will be primarily responsible for the safety of food. Member States will be responsible for ensuring that food hygiene rules are applied and complied with.

HACCP - The use of HACCP (Hazard Analysis Critical Control Points) principles will become compulsory in all sectors of the food business *except* primary production on farms. HACCP involves identifying points in the production chain that are critical to food safety and putting in place, and reviewing, measures taken to minimise risks. Although the application of HACCP principles is not obligatory for primary production (as had originally been proposed), farmers are to be encouraged by Member States to use HACCP as far as is practicable.

Registration/Approval - All food businesses will have to be registered and some businesses, carrying out more hygiene-sensitive activities, such as slaughterhouses, will need to be approved (including an on-site inspection) before they can operate.

Guides to good practice - Food business operators will be encouraged to develop and use guides to good practice for hygiene and for the application of HACCP. If necessary, guides to good practice may be developed at EU level. These will be developed by, or in consultation with, representatives of European food business sectors and other interested parties (such as consumer groups) and in cooperation with the competent authorities. Draft guides will be assessed by the Standing Committee of the Food Chain and Animal Health (comprising representatives of the Member States). The development of guides on the application of HACCP are being encouraged by the EU on the grounds that they may help smaller businesses with limited resources or personnel who are obliged to introduce HACCP.

Flexibility/Exemptions - The food hygiene package allows some flexibility for small businesses, for food producers using traditional food production methods and those in remote geographical areas. The Regulations do not apply to primary production for domestic use or to the direct supply by the producer of small quantities of primary products to the consumer or local retail establishments.

Imports - In order to ensure that imported products of animal origin meet EU safety standards, imports into the Community of food products of animal origin must be from a country that is on a list of countries from which imports of that type of product are permitted. Furthermore, the product must have come from an establishment contained in a list of establishments from which imports into the community of that product are permitted. The list will be established and managed by the European Commission via the Regulatory Committee procedure[1].

1. The Regulatory Committee procedure is designed to facilitate adoption of secondary or implementary legislation and involves formal consultation of the Member States of Commission draft measures. Once the Committee has approved the draft, the Commission may then adopt them.

FEED HYGIENE REGULATION

The feed hygiene Regulation covers all types of feed and all feed business operators. Feed is produced either by using soil resources (such as grass and cereals) or from by-products of the food industry (such as bakery waste). Previously food industry by-products were not subject to specific hygiene rules. This was seen as unacceptable as contamination in the feed chain can lead to contamination in the food chain. It is because of this that the feed hygiene Regulation has been referred to as the "missing link" in the Commission's "farm to fork" approach to food safety. The Regulation introduces HACCP principles for feed production for the first time. It also requires the registration of all feed establishments, thereby extending the current requirements of Directive 95/69 on the registration and approval of certain establishments manufacturing or using sensitive substances such as certain additives.

Main points of the Feed Hygiene Regulation

Responsibility - As with the food hygiene rules, feed business operators are responsible for ensuring feed safety. The Regulation applies to the production of feed at all levels from the primary production of feed crops all the way through to the placing of feed on the market. It applies to feed for food producing animals, including to feed imported into the EU from third countries. The wide scope of the application is intended to improve traceability which will facilitate the removal of contaminated feed, and food produced from contaminated feed, should this become necessary.

Flexibility/Exemptions - The feed hygiene Regulation does not apply to:

- the production of feed for, and the feeding of, animals for home consumption;
- the feeding of non-food producing animals;
- the retailing of pet food; and
- trade between farmers of small quantities of feed at local level.

However, provision is made for Member States to adopt their own national rules in respect of the above if they so wish.

Obligations - The Regulation restates the general obligation of EU food law[2] that only safe feed may be placed on the market. It also sets specific obligations on operators dependent on the activities they undertake and the stage of production in the feed chain. The specific requirements cover areas similar to those currently applying to establishments falling within the scope of Directive 95/69, namely: facilities and equipment; personnel; production; quality control; storage and transport; and documentation and record keeping.

HACCP - One of the major changes brought about by the new Regulation is that all feed businesses (with the exception of those at primary production level) will for the first time be obliged to put in place a system based on HACCP principles. They will therefore need to identify and control those points in production critical to feed safety.

Guides to Good Practice - As in the EU food hygiene legislation, the feed hygiene Regulation makes provision and sets out procedures for the adoption of Community guides to good hygiene practice. These may be of particular importance to primary producers who are exempt from the obligation to implement systems based on HACCP principles. Member States will encourage the adoption of national guides to good practice in cases where EU-level guides are not appropriate. Provision is made for feed business operators to use guides to good practice to help them to comply with their obligations under the feed hygiene Regulation. However, the use of such guides will be voluntary.

Financial Guarantees - The original proposal envisaged an obligation on feed business operators to have financial guarantees in place to cover risks related to their business. These might include, for example, insurance to cover the cost of withdrawing unsafe products from the market. However these obligations were not imposed in the final Regulation following concerns that insurance may not always be available to cover such risks. The Commission has instead been tasked with reviewing the options in respect of potential financial guarantees within 12 months of the Regulation coming into effect (that is by 1 January 2007). Proposals for legislation in respect of financial guarantees may be put forward when the Commission's report is issued.

Approval/Registration - The feed Regulation extends the current system of registration and approval under the Certain Establishments Directive (95/69) to require the registration of all feed businesses in the EU. Some establishments (for example those manufacturing or using certain additives or other sensitive substances) will require prior approval for their activities following an on-site visit.

Imports - Feed imported into the Community from non-EU third countries must meet equivalent safety and hygiene standards to those set out in EU legislation. In order to facilitate this feed may only be imported if it originates in an establishment that is licensed to export feed to the EU by the competent authority of the exporting country. The detailed rules applying to controls on imports into the EU from third countries will be adopted by the Commission in due course via the Regulatory Committee procedure.

REGULATION ON OFFICIAL FOOD AND FEED CONTROLS

The Regulation on Official Food and Feed Controls ("Official Controls Regulation") defines the responsibilities of Member States who are tasked with ensuring that food and feed operators apply and comply correctly with the new legislation. It also sets out how the European Commission can evaluate the performance of Member States' controls.

Under the Official Controls Regulation the Commission's Dublin-based Food and Veterinary Office ("FVO") is responsible for auditing the Member States' performance of enforcement. The Regulation sets out a harmonised approach to the design and development of control systems throughout the EU, including setting out performance criteria to be met by the competent authorities of Member States.

Controls

The Official Controls Regulation introduces new general rules that are applicable to all food and feed production, whether produced in the EU or

2. Regulation 178/2002 on the General Principles of Food Law and establishing the European Food Safety Authority

imported. While specific controls, such as those that deal with zoonoses, residues, pesticides and BSE (Bovine Spongiform Encephalopathy) will remain in place, the following Directives will be repealed when the Regulation comes into effect: Directive 70/373 on sampling and analysis for the official control of feedingstuffs; Directive 95/35 on official inspections in the field of animal nutrition; and Directives 89/379 and 93/99 on the official control of foodstuffs.

The Official Controls Regulation provides that official controls should be carried out using appropriate techniques including routine surveillance checks and more intensive controls such as inspections, verifications, audits, sampling and the testing of samples. Premises, facilities, equipment, machinery, installations and materials may all be inspected. Staff carrying out the controls should receive training, especially with regard to the implementation of HACCP principles so that competent authorities act in a consistent way throughout the Community.

The frequency of official controls should be regular and proportionate to the risk, taking into account the results of own-checks carried out by the business operator and experience from previous inspections. Ad-hoc controls should be carried out if non-compliance is suspected and may be carried out at any time, even if there is no suspicion of non-compliance.

The Official Controls Regulation does not affect the requirements for veterinary checks on feed and food of animal origin set out in Directive 97/78. However imports of feed and food of non-animal origin will be subject to controls based on a multi-annual national control plan drawn up in light of potential risks. This means that if a particular product is known to present a particular risk, then the sampling frequency may be more stringent than for products that are viewed as lower risk.

Sanctions

The Regulation provides that appropriate and dissuasive sanctions should be imposed as breaches of the feed and food law or the animal health and welfare rules may constitute a threat to the health and welfare of humans, animals and/or the environment. Member States can impose administrative or criminal sanctions under their own national laws. Administrative sanctions include the withdrawal or suspension of an approval, withdrawal from the market or destruction of a product, and restrictions on the scope or scale of the operator's activities.

The Commission, together with the Member States within the Standing Committee or on its own initiative, may take special measures if there has been a serious failure in a Member State's control system which may constitute a possible and widespread risk for human health, animal health or animal welfare. Measures may include suspending the placing of certain feed or food on the market and laying down special conditions or measures necessary to protect human, animal or plant health, animal welfare or the environment. These powers may only be invoked after Community controls have revealed non-compliance with EC legislation and the Member State has failed to correct the situation upon request and within the time limit set by the Commission.

Financing of Official Controls

Member States are responsible for ensuring that they have the financial resources available for carrying out official controls. The Regulation gives them the power to raise these funds by whatever means considered appropriate, including through the use of general taxation and the establishment of fees or charges.

The Regulation requires Member States to charge fees:

- where they are currently collecting fees under Directive 85/73 for veterinary checks on products of animal origin from Community establishments;
- where they are currently collecting fees under Directive 85/75 in relation to veterinary checks on products entering the Community from third countries;
- for the approval of feed establishments; and
- where "excess" controls are required following the detection of non-compliance.

When fees are charged by Member States, whether they are compulsory or optional, the level of the fees may be fixed at a flat rate on the basis of the costs borne by the competent authorities over a given period of time, or, where applicable, at the amounts set out in the Annexes which prescribe minimum rates for different types of controls (for example fees applicable to slaughter inspection, fees applicable to cutting plants, fees applicable to game processing houses, fees applicable to milk production). The minimum rates set out in the Annexes will be updated at least every two years through the Regulatory Procedure. Until 1 January 2008 Member States will be able to continue to use the rates currently applied under Directive 85/73 for veterinary checks on products of animal origin from Community establishments.

For a transitional period until 1 January 2008, Member States will be able to continue to use the current rates under Directive 85/73 for veterinary checks on products of animal origin from Community establishments.

In setting fees Member States are to take into consideration:

- the type of business concerned and relevant risk factors;
- the interest of businesses with a low throughput;
- traditional methods used for production, processing and distribution;
- the needs of businesses located in regions subject to particular geographical constraints.

The Regulation also allows Member States to set the fees for specific official controls at a level below the minimum rates specified in the Annexes to take into account the above four factors or when official controls are carried out with a reduced frequency in view of the own-check and tracing systems implements by the feed or food business and the level of compliance found during official controls. Before setting fees at a lower rate Member States must provide the Commission with a report specifying the type of feed or food or activity concerned, the controls performed by the feed and food business concerned and the method for calculating the reduced fee.

The Commission will review the charging arrangements within three years of the Regulation coming into force with a view to extending mandatory fees into other controls.

Katrina Lajunen, Jackie Smith, London

Proposal to recast and amend Directive 91/321/EEC on infant formulae and follow-on formulae

On 6 April 2004 the European Commission released a working document for a proposal to amend and recast Directive 91/321/EEC of 14 May 1991 on infant formulae ("IF") and follow-on formulae ("FOF").[3] The amendments are primarily a response to ongoing discussions at an international level within the Codex Alimentarius and the report of the Scientific Committee for Food ("SCF") on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae which was adopted by the Commission on 4 April 2003.[4] On 7 May 2004 Member States' experts met in Brussels to discuss the proposal and the views of industry. Many welcomed the working document but have requested more time to consider the changes proposed.

DEFINITIONS OF "INFANT FORMULAE" AND "FOLLOW-ON FORMULAE"

The definitions of IF and FOF would be revised to ensure consistency between the two definitions and to take into account the latest definitions in the Draft Revised Codex Alimentarius Standard on Infant Formulae.[5] IF would mean foods for use by infants "up to the introduction of complimentary feeding" and FOF would mean food for use "when appropriate complimentary feeding is introduced". Unlike the previous definitions, there is no mention made of specific ages of application. The UK has suggested that a reference to use by infants over 6 months should be included in the definition for FOF.

3. http://www.foodstandards.gov.uk/multimedia/pdfs/infant2004euworking.pdf
4. http://europa.eu.int/comm/food/fs/sc/scf/out199_en.pdf
5. ftp://ftp.fao.org/codex/alinorm04/al04_26e.pdf Appendix V.

Inclusion of new ingredients

The proposal would require manufacturers to take into account specific factors when considering the inclusion of new ingredients and to systematically review the available data relating to the expected benefits and safety considerations, including as necessary, appropriate preclinical and clinical studies, performed following expert guidance on the design and conduct of such studies. This represents a step beyond the current requirement that the suitability of ingredients need only be established by generally accepted scientific data.

However, the industry is unhappy that the current text places the onus on industry to ensure the use of new ingredients is safe but the assessment of supporting data falls to the Member States if they request such data. Although this is essentially the same text as appears in the existing Directive, the implication of this is that verification of product safety can occur only after a product is already on the market. The Commission has expressed its willingness to consider this point further.

ESSENTIAL COMPOSITION

The essential composition specified in Annexes I and II of Directive 91/321 would be amended in light of the conclusions of the SCF on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae. Important proposed changes include:

- The SCF recommended that the maximum energy content of both IF and FOF should be reduced from 315kJ (75kcal) per 100ml to 295kJ (70 kcal) per 100ml.
- All formulae should be compared to breast milk as the reference protein, and all formulae should match the amino acid profile of breast milk.
- The SCF proposed that the maximum fat level should be reduced to 6.0g/100kcal. Levels for new ingredients including phospholipids, taurine, oligosaccharides, and inositol have also been proposed.
- Glucose and sucrose may be added to IF but only to help camouflage the taste of certain types of formulae.
- Revised maximum vitamin and mineral levels have been recommended by the SCF based on current evidence of safe maximum intakes or, if such evidence did not exist, a maximum level was proposed for guidance purposes.
- Purity criteria would also be adopted in respect of vitamins, minerals and other nutritional substances.

In addition, several Member States raised industry concerns at the meeting in Brussels on 7 May concerning the proposed change in the protein conversion factor for cows' milk proteins from 6.38 to 6.25. Industry concerns centre on the apparent lack of public health need for such changes and the burden to industry with the concurrent increase in 2% protein content of formulae. Concern has been expressed about the inclusion of honey as a permitted carbohydrate source and the risk of infant botulism. The Commission has agreed to look into this. However a request to include a reference to GMOs being prohibited was considered by the Commission to be inappropriate as legislation already covers this issue.

LABELLING AND PRODUCT CLAIMS

The Directive restricts claims on IF to those listed in Annex IV of the Directive. The Commission is considering a request put forward by the UK, that the restrictions on advertising currently imposed in respect of IF be extended to FOF on the grounds that they too are breast milk substitutes. Currently the proposal amends the list of permitted claims and where appropriate extends the list to permit claims concerning ingredients for which conditions of use are to be specified in the future Directive following review of the essential composition described above. In addition, the proposal is to permit statements on formulae that reflect ethical or religious considerations which might influence dietary choices. The Commission has asked for examples of ethical or religious considerations (for example vegetarian, vegan) that could be included to improve the wording of the current draft.

REFERENCE VALUES FOR NUTRITION LABELLING

As the currently drafted proposal would incorporate new reference values (for example recommended daily intakes) for labelling purposes. They accord with the SCF opinion of March 2003 on the revision of reference values for nutrition labelling.[6] The Commission is to give further consideration to the reference values for chromium and molybdenum further due to the lack of biological and nutritional data in relation to these substances.

Kevin O'Connor, London

Draft Commission Directive on foods intended to meet the expenditure of intense muscular effort ("Sports Foods")

The European Commission is currently consulting Member States on a draft Commission Directive which would set out rules on foodstuffs intended to meet the expenditure of intense muscular effort, especially for sports people ("Sports Foods").

BACKGROUND

Council Directive 89/398/EEC established a general regulatory framework for foodstuffs intended for particular nutritional uses or "Parnuts" foods. Parnuts foods are clearly distinguishable from foods for normal consumption owing to their special composition or manufacturing process. Directive 89/398 provides that Parnuts foods must be suitable for their claimed nutritional purposes and marketed in such a way as to indicate their suitability for these purposes.

While Directive 89/398 laid down general rules for the composition, marketing and labelling requirements of Parnuts foods, it also provided for specific Directives to be adopted covering quality, hygiene, labelling, composition and additives for a number of particular types of Parnuts foods. Specific Directives have already been adopted for infant formulae and follow-on formulae (Directive 91/321) (although there is a current proposal to amend and recast this Directive - see above), processed cereal-based foods and baby foods for infants and young children (Directive 96/5), foods intended for use in energy restricted diets for weight reduction (Directive 96/8); and dietary foods for special medical purposes (Directive 1999/21).

The Commission has prepared a draft specific Directive covering Sports Foods. The draft Directive is a working document and therefore may change.

AIM AND SCIENTIFIC BASIS OF THE DRAFT DIRECTIVE

The aim of the draft Directive is to create a high level of consumer protection by ensuring that foods that are marketed on the basis that they address nutritional requirements associated with the expenditure of intense muscular effort are safe for use, are labelled clearly and adequately and provide guidance on healthy consumption.

The draft Directive is largely based on the findings of the Scientific Committee on Food ("SCF"), which conducted an extensive review of Sports Foods. At the time of the review, which began in 1998, the following types of foods were available on the market for sports people: rehydration drinks; energy drinks, powders and tablets; protein concentrates; supplements with specific vitamins, minerals and trace elements; supplements containing substances such as choline, antioxidants and creatine; and sports bars and meal replacement products.

The SCF review assessed four groups of products as follows:

- **Carbohydrate-rich energy foods** - the SCF concluded that these are useful in situations where an athlete has a limited period of time for recovery between bouts of prolonged physical activity.
- **Carbohydrate-electrolyte solutions** - the SCF noted that drinks containing carbohydrates and electrolytes compare favourably to water in terms of improving performance during prolonged physical activity. However the

6. http://europa.eu.int/comm/food/fs/sc/scf/out171_en.pdf

optimum carbohydrate concentration depends on a number of factors. The SCF proposed an energy range of 80-350 kilocalories per litre with at least 75% of energy provided by carbohydrates. It also proposed a minimum level of sodium to stimulate uptake of water and carbohydrates.

- **Protein and protein components** - the SCF noted that the increased requirement for protein during exercise, especially for exercise that requires endurance, might not be met if the total energy intake was comparatively low. The SCF made various recommendations for the protein content of protein concentrates and protein enriched foods.
- **Supplements containing essential nutrients or other food components** - the SCF noted that providing an athlete had an adequate dietary intake there would be no need for additional micronutrients. It further observed that scientific evidence supporting nutrient intakes beyond the recommended daily allowance was inconsistent or lacking.

WORLD ANTI-DOPING AGENCY REQUIREMENTS

The World Anti-Doping Agency (WADA) compiles and maintains a list of substances which are regulated or prohibited for athletes participating in particular sports or in sporting tournaments such as the Olympics. The list is published in January each year but is also updated at different times of the year if this becomes necessary.
The European Commission has indicated that ideally, all foods covered by the draft Directive, especially foods marketed to athletes, should not contain products that are on the WADA prohibited list. However, the consequential need to impose a Europe-wide ban on substances on the WADA list has presented practical difficulties for the Commission. In particular it is not possible to legally introduce a prohibition in EU legislation that relates to a list that is not under EU legislative control. In addition, the Commission does not currently think that it would be possible to compile its own list of prohibited substances. It is, therefore, actively seeking views from the Member States as to how such a ban could be introduced.

CONTENT OF THE DRAFT DIRECTIVE

The intention is to lay down compositional and labelling rules for Sports Foods. It also provides that information should be given about the energy value and principal nutrients found in such foods.

The draft Directive divides foods into four categories which are roughly analogous to the four categories reviewed by the SCF. The four categories are:

- carbohydrate-rich energy foods;
- carbohydrate-electrolyte solutions;
- protein concentrates; and
- protein-enriched foods.

The draft Directive would require that the composition of Sports Foods should be based on sound nutritional principles and that their use in accordance with a manufacturer's instructions should be safe and beneficial.

DESCRIPTION OF PRODUCTS

All products that are regulated by the draft Directive would have to be described as "dietary food for physical activity" or "dietary drink for physical activity". If the product is designed to meet the nutritional requirements of a particular physical activity, then this activity could be included in the name of the product. Where the physical activity is associated with a sport, then the name of the sport could be indicated in association with the product's name.

LABELLING

In addition to existing requirements set out in the EU's general food labelling Directive (2000/13), as currently drafted, the draft Directive would subject Sports Foods to the following additional labelling requirements:

- the available energy would need to be expressed in kj and kcal and the content of protein, carbohydrate and fat, expressed in numerical form per 100g or per 100ml of product as sold and, where appropriate per 100g or 100ml of product ready for use in accordance with the manufacturer's instructions;

- for protein-based products, information on the origin and nature of the protein and/or protein hydrolysates contained in the product;
- for creatine and products with added creatine, detailed instructions on use and advice that warns consumers not to take over 3g of creatine per day;
- where appropriate, information on the osmolality or the osmolarity of the product.

Labelling would also be required to include instructions on the appropriate preparation, use and storage of the product after opening.

COMPOSITIONAL REQUIREMENTS

Foods covered by the draft Directive would also be required to comply with the compositional criteria that are set out in the Annex of the draft Directive. As currently drafted, the main compositional requirements for the four types of products covered are as follows:

- Carbohydrate rich energy food products - at least 70% of the total energy should come from carbohydrates. In the case of drinks, the carbohydrate concentration should be at least 10% of weight by volume and metabolisable carbohydrates should provide at least 75% of the total energy.
- Carbohydrate-Electrolyte Solutions - the energy content shall be at least 340 kl/l (80 kcal/lk) and not greater than 1488 kl/l (350 kcal/l). Metabolisable carbohydrates must provide at least 75% of the total energy.
- Protein Concentrates - at least 70% of dry matter should be protein and the net protein utilisation should be at least 70%.
- Protein Enriched Foods - at least 25% of the total energy must come from protein and the Net Protein Utilisation should be at least 70%.

NEXT STEPS

The draft Directive is at an early stage and is being amended following comments from the Member States. The Commission is still receiving comments from Member States on labelling and composition issues as well as the categories of foods to be included in the proposal. It is anticipated that a revised working document will be circulated to the Member States' experts after the summer. A second meeting of Member States' experts will then be organised to discuss the draft Directive further.

Ilona Prynne, Katrina Lajunen and Jackie Smith, London

EU requirement to list ingredients of animal feed stuffs - English High Court suspends effect of UK regulations implementing EU Directive

INTRODUCTION

In his recent judgment, delivered on 6 October 2003, Mr Justice Davis took the unprecedented step by an English judge of agreeing to suspend the effects of particular provisions (regulation 6 and parts of regulation 10(c)) of *The Feeding Stuffs, the Feeding Stuffs (sample and analysis) and the Feeding Stuffs (Enforcement) (Amendment) (England) Regulations 2003*, SI 2003/1553 (the "English Regulations")[7].

He decided that certain provisions of the English Regulations, requiring animal feed manufacturers to disclose on labels the specific constituent elements of their brand of feed stuffs - including (at the request of customers) exact percentages - was likely to cause "serious and irreparable" damage to those manufacturers' businesses. His decision was prompted by the obvious potential for competitors to benefit from receipt of this valuable information (essentially the confidential feed recipes) at the expense of the manufacturers who had invested a great deal of their resources researching and developing their products in order to market them - ultimately hoping to achieve a commercial return on their investment.

7. See R (*on the application of ABNA Limited & others) v The Secretary of State for Health & another* [2004] EULR 88; and [2003] EWHC 2420 (Admin).

PUBLIC HEALTH PROTECTION

The judge was not persuaded that the "ingredients listing" requirements were necessary to protect public health in the wake of the BSE crisis and the dioxin crisis in Belgium (involving the sale of contaminated cooking oils) - as alluded to in the preamble to the Directive[8]. Further, despite the fact that the Directive had been adopted under Article 152(4) of the EC Treaty[9], the judge expressed his "serious doubts" as to whether public health and safety was in fact advanced at all by the ingredients listing provisions.

In this connection, the judge cited the following statement Commissioner Byrne made to the European Parliament:

> "*The most important fact is the presence of an ingredient in the compound feeding stuff, not necessarily the exact quantities. These exact quantities have a commercial value but are not linked to health protection.*"

And, a little further on:

> "*I believe I am correct in saying that this issue of public health and food safety is related to the presence, rather than the quantity, of what is contained in the compound feeding stuff.*"

Having regard to his "serious doubts", the judge was persuaded that an arguable case had been made by the applicant companies calling into question the validity of the Directive. In the circumstances, he accepted that a reference to the European Court of Justice ("ECJ") was required, to seek a declaration from it on the Directive's validity.[10]

INTERIM INJUNCTION APPLICATION

Having determined to refer the question of the Directive's validity to the ECJ, the most significant and contentious matter which remained to be decided was the manufacturing companies' application to have the relevant provisions of the English Regulations suspended, pending the outcome of the matter before the ECJ. Bearing in mind the fact that the ECJ's decision might easily take two years to arrive, it was consideration of this aspect of the challenge that occupied most of Davis J's detailed judgment.

The judge noted that the manufacturers were right to have made their application for suspension of the relevant provisions of the English Regulations to the national court. Despite the fact that the proposed suspension would, indirectly, suspend operation of European law (that is the Directive), it was established in case law that the manufacturers did not have standing to bring such an application before the ECJ itself. Indeed, the judge noted with interest the attempt by a French company seeking annulment of the offending provisions of the Directive itself before the court of first instance ("CFI") in 2002. This claim was ruled inadmissible for lack of standing.[11]

The judge then addressed in detail the ECJ's decision in *Zuckerfabrik Suderdithmarschen AG v Hauptzollant Itzehoe* [1991] ECR 415 (C-143/88 and C-92/89) - *as affirmed and amplified by it in Atlanta Fruchthandelsgesellschaft mbh* [1995] ECR 1-3763 (C-465/93). These cases established that national courts have the power to suspend by interim order the operation of national measures based on community measures and gave guidance as to the principles to be applied.

FOUR-STAGE TEST FOR NATIONAL COURTS CONSIDERING INTERIM SUSPENSION

Davis J recited the four matters which must be treated as pre-conditions to the grant of interim relief by the national court:

1. The court must entertain "serious doubts" as to the validity of the Community act and (if not already referred) refer the question of validity to the ECJ.

8. Directive 2002/02.
9. As a measure in the veterinary and phytosanitary fields which had as its direct objective the protection of public health.
10. *Foto-Frost* 1987 ECR 4199.
11. The company had not been able to satisfy the strict standing requirements of Article 230 EC, which require an applicant to show that the challenged measure is of "direct and individual concern" to it. This condition is usually only relevant where, for example, a commission decision is directed to a specific company - not in respect of general legislative measures, even where they affect a small section of industry/society.

2. There must be urgency, in that suspension is required to avoid "serious and irreparable" damage to the applicant - pending the ECJ's judgment.

3. Due account must be taken of the Community interest.

4. In its assessment of all those conditions, the court must respect any prior decision of the ECJ or CFI on the lawfulness of the measure in question and/or application for interim relief at Community level.

Having recited the pre-conditions for interim suspension, however, the judge made clear that the approach of the national court need not be "merely mechanistic". In doing so, he referred to the *Atlanta* judgment - which had stressed that the national court must examine the particular circumstances of the particular case before it. This discretion afforded to the national court was particularly relevant when considering the threshold above which the potential harm to an applicant would be considered "irreparable".

SERIOUS AND IRREPARABLE DAMAGE

The judge referred to the CFI's decision in *Pfizer Animal Health SA v Council* [1999] CMLR 79, where that court was not satisfied that "serious and irreparable" damage would have been caused if an interim order was not made. He also referred again to *Zuckerfabrik*, where the ECJ had pointed out that "purely financial damage" could not - in principle - be regarded as "irreparable" (having regard, in particular, to the potential for claimants to seek compensation from the Community under Article 288 EC).

However, despite these ostensibly unfavourable dicta, the judge noted that the ECJ in *Zuckerfabrik* was careful to point out, immediately thereafter, that "the national court must have regard to the individual circumstances of each case". The judge believed it was legitimate, in this context, for the national court to consider (in a case where the damage likely to be suffered was essentially financial in nature) whether or not such damage was likely to be readily quantifiable.

Considering all the evidence, the judge concluded that very existence of some of the manufacturers was threatened, and that all were exposed to an "irremediable effect" on their market shares. In the circumstances, he concluded that "serious and irreparable" damage would be caused to them, if interim relief were denied.

THE COMMUNITY INTEREST

In terms of the Community interest (another important consideration), the judge held that, as a general rule, economic interests would be subordinated to public health interests (citing the *Pfizer* decision). However, significantly, he noted that this important consideration had to be balanced against the cogent argument put forward by the manufactures that the disputed provisions of the Directive had in fact no direct or genuine public health objective.

COMMUNITY UNIFORMITY

Having regard to the principle of Community uniformity, the judge referred to the fact that he had been made aware of corresponding interim relief applications in France, Italy, Scotland and Northern Ireland. In this context, he noted the obligation on him to weigh considerations of the Community interest and potentially affected third parties against the interests of the manufacturers. He noted that if interim relief were not granted the manufacturers would be required irreversibly to divulge trade secrets, and suffer serious and irreparable harm thereby. Alternatively, in the event of non-compliance, they faced criminal sanctions - under a law which might subsequently be ruled invalid by the ECJ.

GRANT OF INTERIM INJUNCTION

Having regard to the fact that the English Regulations were not yet in force, and that an interim injunction would preserve the status quo and not directly interfere with any personal rights in the interim, the judge held that the balance of convenience was in favour of granting interim relief. He re-emphasised his serious doubts as to whether public health and safety was in fact advanced at all

by the provisions of the Directive and held, for all the reasons identified above, as follows:

1. Permission should be granted to seek judicial review of the provisions of the English Regulations.
2. There should be a reference to the ECJ.
3. Confidentiality should be ordered for the identified materials.
4. Interim suspensory relief in respect of the relevant parts of the English Regulations should be grated pending the ECJ's judgment.

EXTENT OF INTERIM INJUNCTION'S EFFECTS

On the matter of the extent of the interim injunction's effects, the judge noted that it was plain as a matter of both Community and English law that any interim injunction should be restricted to the minimum necessary, insofar as it impacted on the provisions of the English Regulations implementing the Directive. That was also the case as a matter of proportionality. Therefore, the interim suspension would apply only to Regulation 6 and the relevant parts of Regulation 10(c) of the English Regulations which were the offensive provisions.

The judge noted that, in the interim period, the manufacturers had not objected to disclosing the existence of feed materials on labels by specific names and in descending order of weight. Their dispute was with the requirement to disclose percentage listings.

COMMENT

It is reassuring to note that national judges, such as Mr Justice Davis, are prepared to make potentially controversial decisions, which have Community-wide implications, where such action is deemed necessary to protect the intellectual property and, in some cases, very existence of EU businesses. With an increasing degree of regulation affecting all industries now emanating from the EU, we can expect to see many more such applications to national courts for interim suspension of measures in the future.

John Doherty, London

EU and Interbrew settle over practices towards Belgian beer wholesale

On 30 April 2004 the European Commission announced that it had closed its investigation into Interbrew's alleged anti-competitive practices in the Belgian wholesale beer market. The Commission's probe, which stretches back to 1999, concluded after Interbrew undertook to amend its existing practices. The Commission found that Interbrew's practices as amended will not be anti-competitive as they "cannot be considered as an abuse of an alleged dominant position in the Belgian beer market".

Interbrew has promised to implement the following alterations to its wholesale practices by 1 January 2005:

- Interbrew offers rebates to wholesalers based on the volume of each beer purchased by the wholesaler. Interbrew has undertaken to the Commission to make this system entirely transparent for each and all of its wholesalers. So far, wholesalers only knew the discount rate corresponding to the volume range in which their own purchases for the various types of beer happened to fall; and the rates corresponding to the volume ranges situated just above and just below that range. Wholesalers will in the future know the rates for all volume ranges.
- Rebates are also granted to wholesalers for the availability of types of Interbrew beer in the wholesaler's tied outlets. These rebates are linked to the number of such tied outlets. In the future, wholesalers will receive a fixed amount per volume of a particular beer they agree to sell in its tied outlets, regardless of the number of tied outlets.
- Management support services are provided by Interbrew to wholesalers with whom Interbrew has entered into a partnership agreement. Under such agreements, Interbrew will no longer have neither a right to access to the wholesaler's confidential business data, nor a right of first refusal to block a competitor's bid for the purchase of the wholesaler's business to enable Interbrew to make its own bid instead.

- Interbrew has promised to terminate its contract with Haacht which is Interbrew's sole remaining distribution contract with a competitor brewer. The Commission said some of Interbrew's beers "have benefited so far from exclusive access" to Haacht's retail outlets.
- Under existing agreements, incentives including financial support and gadgets are offered to wholesalers, usually in return for promotional activities. Interbrew has undertaken to: abolish any product exclusivity requirement; make the eligibility criteria fully transparent; and clarify that the same incentives are open to all wholesalers without exception.

Interbrew, whose best-selling beers in Belgium are *Stella Artois* and *Jupiler*, concluded a complex $11.4bn "alliance" with Brazil's AmBev in March 2004 to form the world's largest brewer by volume. Last year, Interbrew settled a probe concerning its exclusive beer contracts with Belgian retail outlets such as hotels, pubs and restaurants. An obligation had been imposed on 7000 tied outlets that receive loans or other financial assistance from Interbrew to serve exclusively Interbrew beer. Under the settlement with the Commission this was restricted to draught pils only. Arrangements governing Interbrew's relationship with some 3,000 or so other outlets which lease or sublease from Interbrew were also amended. Such outlets are now required only to stock Interbrew's beer exclusively when on draught. This gives competing brewers the chance to sell their bottled or canned beer to such outlets.

Kevin O'Connor, London

Ice Cream Judgment - CFI upholds Commission decision

On 23 October 2003, the European Court of First Instance (the "CFI") held that an exclusivity clause restricting ice-cream retailers' use of freezers supplied by Van den Bergh Foods in Ireland infringed EC competition law.

FACTS

Van Den Bergh Foods, formerly HB Ice Cream Ltd ("HB") is a wholly owned subsidiary of Unilever plc. It is the main manufacturer of impulse ice-cream products (single-wrapped ice-creams for immediate consumption) in Ireland. For a number of years it has supplied retailers with freezer cabinets, in which it retains ownership, for no direct charge on the condition that the cabinets are used exclusively for the sale of HB products.

In 1989, Masterfoods Ltd (a subsidiary of Mars Inc) entered the Irish ice-cream market and persuaded some retailers to include its products in HB freezers. HB responded by enforcing the exclusivity clause in its distribution agreements. The distribution share of Masterfoods' ice-creams subsequently fell from 42% to 20%.

Masterfoods brought an action in the Irish High Court claiming that HB's exclusivity clause infringed domestic competition law and Articles 81 (prohibition on anti-competitive agreements) and 82 (prohibition on the abuse of a dominant position) of the EC Treaty. It also lodged a complaint with the European Commission. The Commission adopted a decision in March 1998 finding that the exclusivity provision in HB's distribution agreements relating to the use of its freezers infringed both Article 81 and Article 82. The Commission also refused to grant the distribution agreements an exemption under Article 81(3). The Commission decision required HB to release the retailers from the exclusivity provision.

The Irish High Court rejected Masterfoods' action and, on appeal, the Irish Supreme Court referred certain questions to the European Court of Justice (the "ECJ"). The ECJ found that, where a national court is considering issues that are already subject to a Commission decision, the court must not reach a judgment which conflicts with that decision.

HB applied to the CFI for an annulment of the Commission decision claiming that the Commission had overestimated the existence and extent of foreclosure, had erred in its application of Articles 81 and 82, had failed to respect HB's property rights as required by the general principles of EC law and had failed to give sufficient reasons for its decision.

CFI JUDGMENT

The CFI dismissed HB's action and upheld the Commission's decision on the following grounds:

Article 81

The CFI considered the following elements in reaching its conclusion that the agreements as a whole restricted competition on the market, and so infringed Article 81:

- The provision of a freezer without charge, the evident popularity of HB's ice cream, the breadth of its range of products and the benefits associated with the sale of them are all very important considerations in the eyes of retailers when they consider their strategy for selling impulse ice-creams (that is whether to replace the HB freezer or to acquire an additional freezer).
- HB had an undisputed dominant position on the market and the CFI found that the Commission was right to take this into account in its assessment. It was relevant to the economic market conditions and the way in which retailers assess the risks and disadvantages of stocking another make of ice-cream. In reality, retailers have only very rarely opted to replace freezer cabinets supplied by HB.
- The measures taken by HB in order to ensure compliance with the exclusivity clause had the effect of causing retailers to act differently in regard to HB's products than they do in regard to the ice creams of other brands. This acted in a way which was liable to distort competition in the relevant market. Despite the popularity of HB's products, retailers would wish to stock ice creams of other brands alongside those of HB, provided that they could do so in the same freezer. The effect of the enforcement of the exclusivity provision was demonstrated by the fact that the distribution share of Masterfoods' products fell from 42% to less than 20% after HB started actively enforcing the provision.
- An exclusivity provision such as HB's has a considerable dissuasive effect on retailers with regard to the installation of their own cabinet or that of another manufacturer and has the effect of a tie on sales outlets that have only HB freezer cabinets. Although it is theoretically possible for retailers who have only an HB freezer cabinet to sell the ice creams of other manufacturers, the effect of the exclusivity clause in practice is to restrict the commercial freedom of retailers to choose the products that they wish to sell in their sales outlets.
- Competing suppliers are in effect prevented from gaining access to the relevant market and from expanding by a series of factors including the burden which the purchase and maintenance of a freezer cabinet represents for retailers, the retailers' aversion to risk and their reluctance to sever established relations with their suppliers. The ability to supply retailers with freezer cabinets and the running maintenance costs of those freezers represents a financial barrier to the entry of new suppliers and to the expansion of existing suppliers.

Article 81(3)

As regards the possibility of the grant of an individual exemption by the Commission, the CFI found that the Commission had correctly concluded that the first of the conditions for exemption in Article 81(3) (that the agreement contributes to the production or distribution of goods or to promoting technical or economic progress) did not apply. According to established case law this condition will only be satisfied where the improvement resulting from the agreement displays appreciable objective advantages for consumers of such a character as to compensate for the disadvantages which they cause to competition[12]. The Commission found that due to the barriers to entry presented by HB's network of agreements and the consequent weakening of competition, this condition was not satisfied. The CFI agreed with this approach.

As the conditions for exemption apply cumulatively, the CFI did not consider it necessary to review the possible application of other conditions in Article 81(3).

12. Joined Cases 56/64 and 58/64 *Consten and Grundig v Commission* [1966] ECR 299

Article 82

Although the CFI accepted HB's argument that the provision of freezer cabinets on a condition of exclusivity constitutes a standard practice on the relevant market, this did not mean that it amounted to the conduct of normal competition by a dominant undertaking. The existence of a dominant player means that competition in the market is already restricted.

The CFI found that the Commission correctly held that HB is an "unavoidable partner" for many ice-cream retailers in Ireland and that it has a dominant position on that market. HB had a share of 89% of the relevant market at the time of the Commission's decision and it has the most extensive and most popular range of products on the relevant market. The CFI found that HB was the sole supplier of impulse ice-creams in approximately 40% of outlets in Ireland, and was part of the multinational Unilever group which has been producing and marketing ice creams for many years in all the Member States and many other countries (where it is often the leading supplier) and that the HB brand is very well-known.

HB had effectively tied 40% of the outlets in the relevant market by an exclusivity clause, which in reality created outlet exclusivity. This amounts to an abuse of a dominant position within the meaning of Article 82. The exclusivity clause has the effect of preventing (or restricting the ability of) the retailers concerned from selling other brands of ice cream. This is despite the fact that there is a demand for such brands. This therefore prevents competing manufacturers from gaining access to the relevant market. The CFI found that the Commission rightly held that HB was abusing its dominant position by inducing retailers who did not have any other ice cream freezer cabinet to accept agreements for the provision of cabinets subject to a condition of exclusivity and maintaining these cabinets free of any direct charge to the retailers.

The CFI also rejected HB's claims that the Commission's decision unlawfully infringed its right to property and that it failed to give adequate reasons for its decision.

CONCLUSION

The CFI judgment fully supports the Commission's application of law and fact. Following on from the earlier German ice-cream cases (*Langnese-Iglo* and *Schöller*) it confirms that, in the context of the market for impulse ice-creams, a network of agreements, which foreclose competition by virtue of requiring exclusive use of supplied freezer cabinets, infringes Article 81. This is the case even where, as in this case, the retailers are contractually free to sell the products of other manufacturers. Further, where the supplier is in a position of dominance the provision and maintenance of such cabinets, without extra charge, infringes Article 82.

The CFI specifically referred to the "wider Community importance" of the issues raised by the Commission decision, in particular in light of the fact that various national courts and competition authorities are dealing with parallel cases raising similar issues. It considered that the Commission decision was appropriate to ensure that the Community competition rules were applied coherently to the various forms of exclusivity practised by ice-cream manufacturers throughout the Community.

This case is currently under appeal to the ECJ.

Emily Gibson, Brussels

WTO dispute continues despite the end of the EU's de facto moratorium

The European Commission authorised on 19 May 2004 the placing on the market of Syngenta's Bt11 genetically modified maize. However, despite this decision the dispute brought before the World Trade Organization (WTO), by Argentina, Canada and the US against the EU's de facto moratorium on the approval of genetically modified organisms is still in place and the Dispute Panel review continues as planned. The parties have already presented their

first submissions and participated on 2 June in the first Panel hearing.

Two independent groups acting in the public interest are intervening in the dispute settlement process by making submissions to the WTO Dispute Panel in the form of amicus curiae (or "friend of the court") briefs. While third parties can file "amicus curiae" there is no obligation on the Panel to take their views into account. One of the amicus curiae has been submitted by a trans-Atlantic group of expert academics and the other one by an international coalition of 15 public interest groups from Europe, the US, Canada, Argentina, Chile and India. The coalition of interest groups claims the WTO should reject the challenge and recognise the legitimate role of the EC and individual countries to establish appropriate mechanisms to make decisions about the desirability of GMOs. The coalition of scholars believes the role of the WTO Panel should be one of reviewing the procedural adequacy of executive decision-making processes in the various jurisdictions involved, rather than one of arbitrating on the substantive merits of the individual risk assessments themselves. The ruling of the WTO Panel is expected in early September.

While it has been claimed that the approval of the Bt11 GM maize ends the EU's de facto moratorium, it does not imply that the WTO dispute is or should be terminated. The WTO proceedings can be terminated either by (i) the complainants request to suspend the proceedings or (ii) the parties notification to the WTO Dispute Settlement Body that they have reached a mutually satisfactory solution which puts an end to the dispute.

It is very likely that the complainants will proceed cautiously at first and that they will not request the suspension or termination of the proceedings until there are clear indications from the EU Member States and European Commission that the requests for GMO authorisations which are currently in the pipe-line will receive a positive response, meaning that they will be able to be marketed in the EU.

Iciar Chavarri, Brussels

Commission relaxes wine labelling rules for non-EU producers

On 24 February 2004, the European Commission adopted Regulation (EC) 316/2004 to permit wine producers located outside the EU to use "traditional expressions" to describe and label their wines when sold within the EU market. "Traditional expressions" are terms used historically to designate quality wines by reference to colour, quality or a particular production or ageing method. Terms such as "*tawny*", "*ruby*", "*hock*" and "*Est Est Est*" may now be used by non-EU countries to describe wine sold within the EU provided that such non-EU third countries can demonstrate observance of a criteria designed to ensure quality.

The Regulation was introduced by the Commission principally to ensure conformity of EU legislation with the EU's international commitments under the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIP) and the General Agreement on Tariffs and Trade (GATT). Under the previous controls imposed by Regulation (EC) 753/2002, some traditional expressions such as "*fino*" and "*claret*" which had been used for a long time in other parts of the world were prohibited from appearing in the EU market on the labels of wine produced by third countries. Franz Fischler, European Commissioner for Agriculture, Rural Development and Fisheries, commented: "The nature of the conditions which have to be fulfilled by third countries for the use of EU traditional expressions ... constitute a guarantee against any abusive use. These amendments enhance the protection of interests of producers and consumers, market transparency and fair competition, which the regulation on wine labelling was set off to safeguard, and a response to our international level commitments."

Regulation 753/2002 had established a system of two categories of traditional expressions. The first category contained expressions such as '*château*', '*classico*' and '*reserva*' whose use by a third country was permitted under certain conditions. The second category was reserved exclusively to describe wines produced in the EU and contained expressions linked to production in particular geographical areas

such as '*toscarno*', '*amarone*', and '*vin jaune*'. The new Regulation simplifies this system by merging the two categories into a single category. A third country will be allowed to use any traditional expression provided the country proves to the satisfaction of the Commission and Member States that the term:

(a) has been used in the country for at least ten years;

(b) is recognised and governed by rules which apply to wine producers or laid down by representative producer organisations and which do not mislead the consumer regarding the term;

(c) is specific; and

(d) is distinctive and/or enjoys a reputation in the country.

A further requirement has been set that only traditional expressions in the official language of the third country in question can be authorised. The use of an expression in a language other than the official language will only be allowed where the use of that language is provided for in the legislation of the country concerned and where the traditional expression in question has been in continual use in the country for a minimum of 25 years. This final requirement will cause particular concern for producers in Spain and France given the particularly widespread use of Spanish and French in wine-producing third countries.

The amendments were passed by the Commission despite strong opposition from most major wine-producing Member States - first and foremost Italy but also France, Spain, Greece, Portugal and Luxembourg. Giuseppe Martelli, president of the Italian wine association, "Assenologi" said: "The reason for this turnaround is a political one, in response to the WTO's pressure and accusation of EU protectionism. We risk losing our cultural and territorial heritage by falling right into the hands of wine-pirates. Non-EU countries will legally be able to sell *Brunello* from Argentina, *Amarone* from South Africa, *Morellino* from New Zealand, *Recioto* from Australia or *Vin Santo* from Chile."

The amendments should provide the Commission with additional flexibility in its negotiations with foreign wine producing countries, in particular the US and Australia. Negotiations with Australia, aimed at finalising the 1994 EU-Australia Wine Agreement, were scheduled to resume in Brussels on 1 April 2004 and will cover the protection of intellectual property relating to geographical indications and traditional expressions. Last December the EU extended a temporary wine imports and exports deal with the United States, but failed to reach agreement on the use of names such as Chablis, Burgundy and Chianti.

Kevin O'Connor, London

China addresses the problem of fake food

BACKGROUND

In the last edition of this update, we featured the Hong Kong Government's public consultation on a nutrition labelling scheme for pre-packaged foods. Since that article a disturbing related issue has emerged in Hong Kong and mainland China. Most people are familiar with the trade in counterfeit items all over the world such as watches, computer games, DVDs and clothing. Whilst this is a major concern for multi-national and local companies who wish to protect their intellectual property rights, the increasing problem of "fake foods" is obviously of a greater human concern. The range of fake foods and the "ingredients" is quite astonishing:

- in Fuyang, at least 12 babies have died of malnutrition after being fed with substandard milk powder made of starch, sugar, milk essence and other cheap ingredients but deficient in protein, fat and vitamins which are necessary for infants' growth. In addition, 229 malnourished babies that have survived are now suffering from swollen heads;
- in Chengdu, a brand of pickled vegetable was found to contain six times the national standard of the preservative sodium benzoate;
- in Guangzhou, rice wine has been found to contain industrial methanol causing blindness. At

least 9 people died and more than 50 were hospitalized;

- in Foshan, concentrated sweetener, caramel colouring, organic ester and preservatives were bottled and marketed as "iced tea" which could cause damage to the kidneys and other organs;
- in Hong Kong, counterfeit soya sauce has been seized which was manufactured from human hair.

As is common with other counterfeit goods, fake foods are usually cheaper than the genuine articles and tend to have errors or differences on the labels. In fact, the problem is not just limited to counterfeit and substandard foods. There are also serious problems in mainland China with counterfeit pharmaceuticals and car-parts.

CURRENT REGULATORY FRAMEWORK

These incidents have again put into focus the need for the central government to tackle the wider problem of fake and unhygienic food produced by numerous counterfeiters. This problem has existed in mainland China for many years. In 2003, the National People's Congress - the top legislative body - set up the State Food and Drug Administration ("SFDA") in response to persistent complaints about substandard food products and numerous cases of mass food poisoning. The extent of the SFDA's mandate remains unclear and one year into its existence, the food safety problem remains and indeed seems to have become worse. Although the SFDA has the power to implement food safety regulations, it needs to rely on other government departments to enforce the regulations.

There are three major reasons for the recent worsening of the situation. First, mainland China does not have a complete food safety law system in place to regulate the production, processing and circulation of food. Second, there is a lack of a unified food examination and supervision system. Third, government departments have been lax in enforcing food safety regulations and carrying out inspections.

The Product Quality Law and the Food Hygiene Law are the basic laws governing the quality or hygiene of food in mainland China. These laws only lay down general principles and lack detailed rules to regulate the food processing chain from farm to table. Meanwhile, in recent years, many new technologies have been adopted in the food industry and new ingredients have been added in the production to make food attractive and increase consumer interest. However, legislation has not kept pace with these new developments which could pose further threats to public health.

Lack of a unified food examination and control system has affected the efficiency of food quality supervision. Currently, more than one government department is responsible for the supervision of food safety. The Administration of Industry and Commerce is responsible for overseeing the distribution of food to supermarkets, the Administration of Quality Supervision is responsible for examining food production and processing, the Ministry of Health is in charge of food hygiene in restaurants and the Agricultural and Forest Departments are responsible if agricultural products or wildlife are involved respectively. Co-operation between these government departments is not close and they do not share information.

Government officials have also been lax in taking measures to crack down on the counterfeiting. This is particularly a problem where the counterfeiters are companies owned by local government. According to some reports counterfeit manufacturers are common in parts of mainland China and are a source of income for local authorities with the counterfeiters being protected through corrupt officials and bribery. In addition, penalties under the current legislation are too lenient to deter the counterfeiters (except in cases where death or severe consequence is found and criminal liability will be imposed). For example, under the Food Hygiene Law, the fine for the producer of the substandard milk powder is between RMB 1,000 to 50,000 (approximately € 100 to 5,000).

FUTURE DEVELOPMENTS

It is hoped that now these stories have caused national and international publicity it will encourage enforcement of product liability and quality legislation in mainland China. Indeed in Berlin recently, Premier Wen Jiabao announced a

crackdown on fake foods and pharmaceuticals (as well as other pirated goods) and said that he was to assign a vice-premier to the fight against fakes and was looking at other measures to curb the practice. Mainland China also has recently launched a seven month food safety campaign across the country to regulate the production, processing, circulation of food to ensure the nation's food safety. The central government has taken steps to build up a social credit system in the food sector by 2008, under which the public will play a supervisory role and food providers will be subject to a grading system.

In Hong Kong the Customs and Excise and Food and Environmental Hygiene Departments ("FEHD") recently have been active investigating substandard and counterfeit foods imported into Hong Kong from mainland China. The FEHD's investigation is ongoing with a particular emphasis on levels of additives such as preservatives, colourings and sweeteners and has indicated the results will be available in the next few weeks.

The problem may seem far away from Europe and elsewhere but it may only be a matter of time before this problem becomes an issue closer to European homes. Counterfeit goods may be imported into the grey market and obviously multi-national food manufacturers and suppliers who export goods to the mainland China and other regions where such counterfeiting is a problem may be affected just like those who manufacture computer games and clothing. However, the consequences are much more tragic.

Andrew Dale, Hong Kong
Zhen Feng, Shanghai

HOW TO CONTACT US

Please do not hesitate to contact any of the following regulatory practitioners or the persons at Lovells with whom you normally deal.

Regulatory		
London	**Telephone**	**Email address**
Andrew Skipper	00 44 20 7296 2923	andrew.skipper@lovells.com
Richard Welfare	00 44 20 7296 2000	richard.welfare@lovells.com
Jackie Smith	00 44 20 7296 2000	jackie.smith@lovells.com
Ali Tyebkhan	00 44 20 7296 5286	ali.tyebkhan@lovells.com
Brussels		
Chris Thomas	00 322 647 0660	christopher.thomas@lovells.com
Debra Holland	00 322 647 0660	debra.holland@lovells.com
Helen Pope	00 322 647 0660	helen.pope@lovells.com
Jacques Derenne	00 322 647 0660	jacques.derenne@lovells.com
Amsterdam		
Bert Oosting	00 31 20 55 33 763	bert.oosting@lovells.com
Elly Koning	00 31 20 55 33 650	elly.koning@lovells.com
Paris		
Carol Arribes	00 331 536 74 747	carol.arribes@lovells.com
Rome		
Isabella Betti	00 390 6675 82352	isabella.betti@lovells.com
Leah Dunlop	00 390 6675 82348	leah.dunlop@lovells.com
Paola La Licata	00 39 06 67582334	paola.lalicata@lovells.com
Hamburg		
Thomas Salomon	00 49 40 419 930	thomas.salomon@lovells.com
Susanne Karow	00 49 40 419 930	susanne.karow@lovells.com
Munich		
Uwe Froehlich	00 49 89 290 120	uwe.froehlich@lovells.com
Hong Kong		
Andrew Dale	00 852 2840 5045	andrew.dale@lovells.com
Shanghai		
Zhen Feng	00 86 21 6279 3155	zhen.feng@lovells.com