



# EU Analyst: Environment & Life Sciences

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### 1. "REACH" CHEMICALS CONTROL REGULATION ADOPTED

By [Jim Searles](#) and [Darren Abrahams](#)

#### Overview

In December 2006 agreement was reached on the new EU chemicals regulatory regime. Contained in [Regulation \(EC\) No. 1907/2006](#), concerning the Registration, Evaluation and Authorisation of Chemicals ("REACH"), it comprises 141 Articles and 17 Annexes, covering a total of 849 pages. It is mammoth in its concept, in its detailed rules and in the burden for parties in the supply chain who must comply. It is expected to affect the placing on the EU market of some 30,000 chemical substances, imposing major administrative responsibilities and costs on EU producers and importers of these substances. Downstream users, including producers of finished articles incorporating these substances, will be significantly affected as well.

The key elements of REACH are summarised below but a detailed examination in its entirety is essential to ensure that all steps are taken to comply with the various requirements within the applicable deadlines, and of course to ensure ongoing compliance. Manufacturers or importers cannot place a substance onto the EU market unless it is registered in a timely fashion and, if necessary, has secured authorisation (the "no data, no market" principle). This prohibition also concerns use of substances by EU

downstream users and by non-EU producers who want to export products containing a given substance to the EU. Everybody in the supply chain must be aware of how REACH can affect their operations and ensure that all requirements are fulfilled up and down the supply chain. *REACH will enter into force on 1 June 2007*, meaning that suppliers and users must actively prepare themselves. *Steptoe will shortly be announcing a one day seminar devoted to practical compliance with REACH (in Washington, with access by telephone for those who cannot be present). If you wish to be notified of further information on this conference please e-mail [events@steptoe.com](mailto:events@steptoe.com).*

#### REACH policy objectives

The central policy objective is to transfer responsibility for the generation of data on the safety of chemical substances from governmental authorities to the parties placing them on the EU market. This objective covers substances used on their own, in preparations or incorporated into finished articles. Placing on the market means supplying or making available to a third party, whether for payment or free, including importation into the EU. Another key objective is transparency, to be achieved initially by requiring registration with the newly established European Chemicals Agency (the "Agency") of all chemical substances placed on the market; registration will entail submission of detailed information about the substance, its uses, related risks and guidance on safe use. Transparency also entails making certain (non-confidential) information available throughout the supply chain as well as to final consumers, e.g., concerning certain dangerous substances ("substances of very high concern") in the finished products they purchase.

#### Registration by manufacturers/importers

The registration of substances manufactured or imported in quantities of 1 tonne or more, whether on their own, in preparations or finished articles or as intermediates, is the fundamental requirement of REACH. What specific information has to be submitted for the registration, and when the

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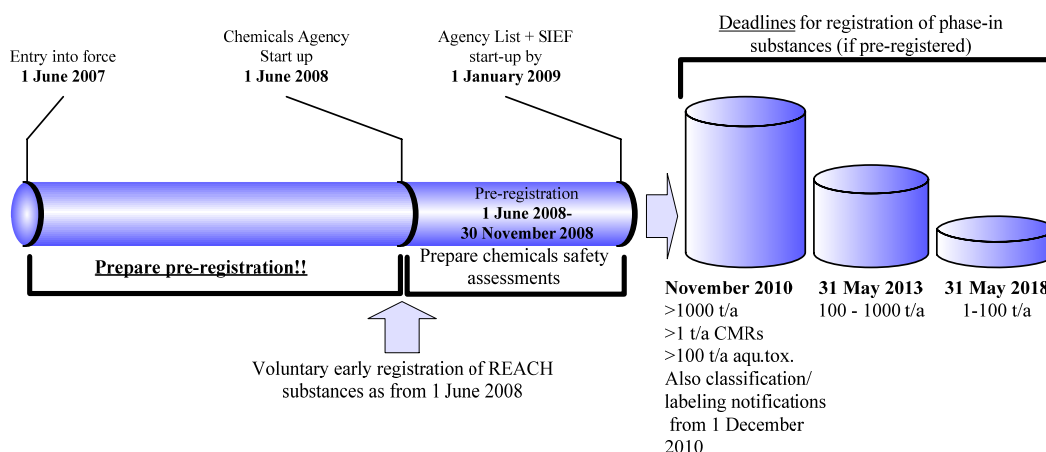
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registration must be made, depend on the hazard of the substance in question and the volume manufactured or imported (summarised below). The Regulation provides for transitional registration periods for so-called “phase-in” substances (mainly substances listed in the European Inventory of Existing Commercial Chemical Substances – [EINECS](#)) according to the volumes manufactured or imported but *only if the substances in question are pre-registered between 1 June and 1 December 2008*.

Downstream users (“DUs”) of a substance that have not been pre-registered may ask the Agency to extend the pre-registration period by 6 months to give them time to find a supplier or to pre-register the substance themselves. DUs are defined as any EU natural or legal entity that uses a substance in the course of its industrial or commercial activities, excluding distributors and consumers. The Agency must publish a list of the pre-registered substances by 1 January 2009 and DUs can see from the list whether the substance of concern has been pre-registered or not. If properly pre-registered, the transitional *deadlines for registration of phase-in substances* are:

- 30 November 2010 for phase-in substances i) manufactured or imported (“M/I”) in quantities  $\geq 1,000$  tonnes per year per manufacturer or importer, ii) substances classified as very toxic to the aquatic environment and M/I in quantities  $\geq 100$  t/a per manufacturer or importer, and iii) substances classified as carcinogenic, mutagenic or toxic to reproduction (“CMRs”) M/I in quantities  $\geq 1$  t/a per manufacturer or importer.
- 31 May 2013 for phase-in substances M/I in quantities between 100 and 1000 t/a per manufacturer or importer.
- 31 May 2018 for phase-in substances M/I in quantities between 1 and 100 t/a per manufacturer or importer.

## Essential Dates for REACH Compliance



Substances that must be registered but which miss the pre-registration period cannot benefit from the above transitional deadlines and become subject to the “no registration, no market” rule, i.e., the party is barred from placing the substance on the EU market pending proper registration.



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The data required for pre-registration is not extensive (name of substance including CAS and EINECS number, contact body, foreseen deadline for registration and tonnage band). However, many companies will have substantial work to identify all of their substances (substances on their own, all substances in preparations, substances in finished products) that are subject to the REACH registration requirements and to ready the files for the pre-registration. Each substance needs to be individually pre-registered.

## Content of registrations

All registrations must include, at minimum, the “technical dossier”. The technical dossier will include the identity of the manufacturer/importer, identity of the substance, information on the manufacture and use(s) of the substance, the classification and labelling of the substance, exposure information, and guidance on safe use. Study summaries (or robust study summaries in specified cases) must also be provided concerning information derived from testing required under Annexes VII to XI – the level of testing required varies according to the tonnages manufactured or imported (e.g., the most extensive testing applies for substances M/I in quantities  $\geq 1,000$  t/a). If further testing is needed, proposals must be submitted first.

In addition, chemical safety assessments and a chemical safety report (“CSR”) are required for substances M/I in quantities  $\geq 10$  t/a. The CSR sets out the hazards and classification of the substance and whether it is persistent, bioaccumulative and toxic (“PBT”) or very persistent, very bioaccumulative (“vPvB”). The CSR must also provide exposure scenarios, including recommendations for measures to ensure that risks to humans and the environment are adequately controlled, regarding the registrant’s own uses and all uses identified by DUs in the chain. If the assessment is required but a DU does not notify its use to its supplier/registrant or uses a substance outside the conditions covered in the registrant’s CSR, the DU itself must perform the safety assessment concerning its uses.

## Data and cost sharing

Given the extent of data that must be generated for an individual registration, the Regulation provides for sharing of data, tasks and costs. The above-noted pre-registration of phase-in substances, for example, results in establishment of a Substance Information Exchange Forum (“SIEF”) for each substance. Each SIEF will group all intended registrants of the particular substance (manufacturer, importer, potentially also DUs or other holders of information on the substance) and enable them to share certain information and determine, for example, which studies are available and/or still need to be carried out. Owners of full study reports are required to permit reference to existing vertebrate testing reports and, if requested, also concerning non-vertebrate testing reports. The SIEF parties must agree on generation of any required new testing. Costs for testing must be shared fairly. Fines might be imposed if a study owner refuses to provide either proof of the cost of its study (for purposes of cost sharing and, upon payment, granting permission for the other party to refer to the full study report in its own registration) or the study itself.

In the case of non-phase-in substances and registrants of phase-in substances who have not pre-registered, each potential registrant must inquire to the Agency if a registration has already been submitted for the substance in question. If so, it will be put in contact with previous registrants in order that information and costs can be shared if necessary in order to make the registration.

Also to help reduce registration costs, the Regulation provides that certain data (e.g., on hazardous properties of the substance and classification) should normally be submitted jointly. Thus, a “lead registrant” would submit the data with the agreement of the other registrants. Specified other data must be individually submitted. Certain data, including the CSR, can be submitted jointly but nonetheless might be submitted separately if, for example, this would result in disclosure of commercially sensitive

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information or a joint submission would be disproportionately costly to the company in question.

## Substances in articles

A special regime applies concerning substances contained in articles. "Articles" includes finished products ranging from clothing, marking pens and toys to air conditioners, computers and vehicles. Clearly, many articles placed on the EU market contain a large number of substances that are subject to REACH, with some of these substances being potentially dangerous if released from the article during its use.

REACH requires that all substances *intended to be released* from articles during normal and reasonably foreseeable conditions of use (e.g., ink from cartridges) must be *registered* by the producer or importer according to the normal REACH rules (including pre-registration, volume deadlines and information rules) if those substances are present in the articles above 1 t/a per producer or importer.

In addition, the producer or importer must *notify* the Agency and provide certain specified information for each substance in the article that meets the "substances of very high concern" ("SVHC") criteria *and* is identified in the "candidate list" of substances considered by the Agency to meet the SVHC criteria *if 3 conditions apply*: (i) the substance is present in those articles in quantities totalling over 1 t/a per producer or importer, (ii) the substance is present in those articles above a concentration of 0.1% weight by weight (w/w), and (iii) the producer or importer cannot exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use of the article including disposal. Upon the notification, the Agency can further require full registration of any substance in the article if the volume criterion is met and the Agency "has grounds for suspecting" that the substance is in fact released and presents a risk to humans or the environment.

Note that these provisions on registration/notification of substances in articles do not apply to substances that have already been registered for that use.

Importantly, non-EU manufacturers can appoint a single natural or legal person in the EU to fulfil the REACH obligations that must otherwise be carried out by each importer in the manufacturer's supply chain; in that case the actual importers are deemed to be DU.

## Authorisation of SVHC

Annex XIV of REACH will comprise a list of substances determined to be of very high concern in respect of human and environmental safety. Substances to be listed in Annex XIV are those which meet the criteria set out in Article 57, including CMRs, PBTs, vPvBs as well as certain other substances, such as endocrine disrupters, for which there is scientific evidence of probable serious effects "which give rise to an equivalent level of concern". A producer, importer or downstream user can only place a substance on the market which is included in Annex XIV if, *inter alia*, the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article has been properly authorised.

Applications for authorisation can be made by one or several parties, can cover one or several substances if they are part of the same group and can concern one or multiple uses (own uses and/or uses intended downstream). The application must include an analysis of potential alternative substances (including any relevant R&D undertaken by the applicant) and, if suitable alternatives exist, a substitution plan including a timetable for actions proposed by the applicant.

The provisions on authorisation criteria distinguish between the different hazard classifications and situations where safety thresholds can or cannot be determined. In general, authorisations will be granted if the risk to humans/environment is "adequately controlled". However, more restrictive conditions apply concerning (i) CMRs and certain other SVHC for which safety thresholds are not possible to determine, (ii) PBTs and vPvBs, and (iii) other SVHC identified as having PBT or vPvB properties. In these cases, authorisation can be granted only if it is shown that socio-economic benefits outweigh the risk to human health or the environment and there are no suitable

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alternative substances or technologies. In this context, consideration will be given to, *inter alia*, the information submitted by the applicant and/or other parties concerning alternatives.

Decisions on suitability of alternatives will take into account technical and economic feasibility for the applicant and whether substitution would actually result in reduced overall risks. When granted, authorisations will be subject to time-limited reviews determined on a case-by-case basis and normally subject also to conditions, such as monitoring.

## Information in the supply chain

Suppliers of substances and preparations must provide recipients with safety data sheets ("SDS") whenever a substance or preparation is classified as dangerous, is a PBT or vPvB or is listed in the candidate list for substances requiring authorisation for other reasons. Instances are also specified for when an SDS is required or not. Importantly, REACH requires any supplier of an article containing a SVHC to provide recipients (at no cost) with available information to allow safe use including, at a minimum, the name of the substance. Also in these circumstances the supplier must provide the same information to any consumer who requests it.

## Classification and labelling inventory

Any manufacturer, producer of articles or importer who places a substance requiring registration on the market must provide information to the Agency to enable it to compile, and keep updated, a classification and labelling inventory that will be publicly accessible. The obligation to supply this information will apply from 1 December 2010.

## Action items

It is evident that REACH imposes significant and complex obligations on all parties placing chemical substances onto the EU market, whether on their own, in preparations or in finished articles. This overview is necessarily brief and incomplete. It is essential for companies to understand all of the requirements

applying to them and their supply chain and to prepare to comply, including:

- Prepare an inventory of substances placed on the EU market as a manufacturer and/or importer (substance on its own, in preparation or in article) (possible multiple roles within same group)
- Verify REACH requirements for each substance and sufficiency of own data on each substance having regard to total data needed per the volume band of registrant and substance classification (note some substances may be exempt from registration requirements but not other information requirements)
- Anticipate REACH SIEFs per substance and how to meet own and other parties' data needs (sharing of existing data/costs, generation of necessary new tests/data; joint registration criteria)
- Consider partnerships/consortia to manage data/cost sharing and protection of confidential business information; if non-EU manufacturer, decide whether to use "single representative"
- Identify other parties in the supply chain and respective REACH responsibilities and confirm that each intends to comply (DUs particularly to confirm registration/authorisation upstream for your uses)

Finally, the Commission will publish technical guidance documents for industry in early-mid 2007 and roll out new software packages to facilitate compliance, but preparatory measures can and should already be undertaken. Our experience in assisting companies to understand and achieve compliance with other EU substance control regulations (e.g. hazardous substances in electrical and electronic products) confirms that early action is crucial.

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## 2. LATEST DEVELOPMENTS IN EMISSIONS TRADING

By [Laura Atlee](#)

### Overview

Any hope of reprieve from increasing regulation of greenhouse gas emissions can be forgotten, particularly following the issuing of the UN's Intergovernmental Panel on Climate Change's ("IPCC") 4<sup>th</sup> Assessment Report on 2 February (see in particular the first [report](#) of three in the 4<sup>th</sup> Assessment). The IPCC's report concludes, in part, that the world's temperature will increase by approximately 3°C this century. In the face of these results, any forthcoming international agreements may require industrialised countries to decrease their emissions by 60-80% by 2050.

The European Commission ("Commission") has recently taken a number of initiatives which will significantly affect the future of emissions trading of greenhouse gases in the EU. The [Emissions Trading Directive](#) (Directive 2003/87/ Commission) is a key part of the EU's response to fulfilling its commitments under the [Kyoto Protocol](#) on climate change. The Directive created an Emissions Trading Scheme ("EU ETS") in European Union Allowances ("EUAs"). One EUA is equal to the right to emit one tonne of CO<sub>2</sub> and the total number of EUAs is capped. At the beginning of each trading phase every installation falling within the EU ETS is allocated a certain number of EUAs free of charge. Phase I covers 2005 to 2007 and Phase II 2008 to 2012. Crucially, the number of allowances allocated to an installation may be less than the number of tonnes of CO<sub>2</sub> it emits throughout the year. If the operator of an installation believes that it will not have sufficient EUAs it can buy additional allowances, change its means of production to decrease the tonnes it emits, and/or participate in Kyoto Flexible Mechanisms (i.e. Clean Development Mechanism ("CDM") and Joint Implementation ("JI" explained further below). During the first trading period businesses excluded from the EU ETS may be subject to increased energy costs but are otherwise largely unaffected. This is unlikely to continue much longer for the following reasons:

- The Commission's assessments of the first and second sets of national allocation plans ("NAPs") submitted by EU Member States for Phase II have reduced the number of allowances installations under the EU ETS will receive for free. Thus, abatement costs may be passed along to those outside the EU ETS to a greater extent.
- The EU ETS may be expanded to include additional sectors and/or additional climate change gases; industries that were previously spectators will become participants.
- If the proposal to include aviation is adopted, distribution costs are likely to increase due to the passing on of compliance costs.

### The Phase II trading period

On 29 November 2006, the Commission issued Decisions on NAPs submitted by Germany, Greece, Ireland, Latvia, Lithuania, Luxembourg, Malta, Slovakia, Sweden, and the United Kingdom for the Phase II trading period (summarised in [Communication](#) of the same date) and on 16 January 2007 issued Decisions for [Belgium](#) and [the Netherlands](#). In every case it concluded that the proposed NAP failed to meet at least one of the mandatory criteria required by the Directive. Member States' treatment of the following areas was found particularly lacking:

- *Over-allocation:* In total, the Commission slashed 73.29 million allowances from the proposed NAPs. The UK's NAP is the only plan that does not require a decrease in the number of allowances to be allocated.
- *Ex-post adjustments:* The Commission has reasserted the Directive's requirement that Member States decide the absolute quantity of allowances allocated *before* the trading period starts. Adjustments are only permissible after installations are issued in two specific situations: (1) where an installation is closed during the period the State may determine that there is no longer an operator to whom allowances will be

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issued; and (2) new entrants receive allocations from a reserve, that has been fixed upfront.

- Consistency with supplementary obligations:* As already noted, Member States and EU ETS installations may take supplementary measures in other countries and use credits from these for compliance purposes towards part of their emission reduction commitments. (CDM allow an installation or Member State to carry out projects to reduce emissions in developing countries. JI takes place in a country that has obligations under the Kyoto Protocol.) The Commission had found that the limits on the use of this mechanism by installations were not always respected. Installations (and Member States) are not supposed to rely heavily on CDM and JI; they are supposed to reduce their emissions. The absolute percentage of credits that may be derived from CDM and JI is one half of the reduction the respective Member State must undertake, which is calculated using information from base year emissions (in the 1990's), 2004 emissions, and projected 2010 emissions. If the Member State does not have to rely on CDM and JI to meet its target reduction it may allow the installations to make use of the credits to the full amount of the limit. If the Member State must partially rely on these types of credits, the number available to installations decreases accordingly.
- Issues specific to individual plans:* State specific issues concerned allocation guarantees applying beyond the trading period, banking of allowances, auctioning and the definition of combustion installations. Member States draw up their NAPs under the influence of their national authorities, industries and private citizens; they must make the proposed NAPs open for public consultation. Therefore variances exist. For example, one proposed NAP included a provision on allocation guarantees, which would ensure that an installation would receive a certain number of allowances at no cost following the expiry of Phase II.

At the time of writing, the Commission had not released its Decisions on the remaining 15 NAPs. Nonetheless, the Commission is expected to continue to take issue with the number of allowances Member States propose to allocate. Indeed, a glance at the current market shows that over the past three months the daily price of allowances has dropped from almost €12 to just below €4, which has been partially attributed to their over-allocation. The Phase I Trading Period "honeymoon" will come to an abrupt end in 2008. The Commission will, in all probability, learn from the lacunas exposed during the first two years of trading.

## Changes to the Directive

The Emissions Trading Directive has a built-in review mechanism. In the autumn, the European Climate Change Programme Working Group will begin the process of considering amendments to the Directive in order for these to be implemented by way of legislative amendment in time to take effect in the Phase III Trading Period (post-2012). As is evident from past NAP reviews, the Commission is particularly concerned with the total number of allowances allocated. Indeed, the entire "cap and trade" system rests on the principle that only a limited number of allowances are on the market. The review will be focused on four categories: the scope of the EU ETS Directive, further harmonisation among Member States, compliance and enforcement of obligations and linking the EU ETS to other schemes. Each category includes issues that could heavily impact (potential) participating installations. Other changes include:

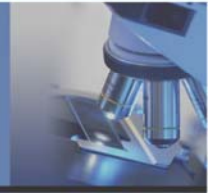
- Scope of the Directive:* Certain small installations may be dropped from the EU ETS. Additional gases and sectors that may be added to the scheme include N<sub>2</sub>O and CO<sub>2</sub> from the production of ammonia, CH<sub>4</sub> from coal mines, CO<sub>2</sub> from the production of petrochemicals, CO<sub>2</sub> and PFCs from the production of aluminium and CH<sub>4</sub> from coal mines. Aside from the suggestions made by the Commission, an independent [report](#) funded by the Commission, produced by Ecofys, on the inclusion

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of additional sectors and gases into the EU ETS, has suggested that CO<sub>2</sub> emissions in the gypsum production, stone wool production, and waste incineration sectors could all be included.

- *Further Harmonisation:* A single EU-wide cap (as opposed to national caps) and full auctioning will be considered. If national caps are maintained, they may be determined up-front in the Directive rather than in NAPs. New entrants could be required to buy allowances in the market or at auction. Benchmarking and sector-specific allocation methodologies are also possible.
- *Compliance and Enforcement:* More elaborate provisions governing third party verification of emissions reports and the accreditation process for approving verifiers may be included. On-site visits may become part of the enforcement procedure.
- *Links to third countries:* The EU ETS could be linked to both third countries' trading schemes as well as regional trading schemes. This would enable association with schemes such as the one in California.

EU industry has only 6 years to prepare for these potentially major changes. Assuming, for example that gypsum production were added to the EU ETS, a company considering construction of a new installation will have to address questions such as:

- Do we build in a CO<sub>2</sub> restrained Member State, like Spain, or one that has more room to grow such as Latvia?
- Should we install more advanced, cleaner equipment or will we receive enough EUAs for free?
- If we do not receive enough EUAs to cover our emissions, will we buy them on the market or decrease production?

Such a simple example clearly illustrates that now is the time for strategic decisions to be made.

## Inclusion of aviation

There has been uproar from the aviation sector in the EU, and beyond, in response to the Commission's [proposal](#) to include the sector. US operators, in particular, have challenged the idea that from 2012 the scheme would cover all flights arriving at or departing from an airport in the Community. From 2011, all intra-EU flights will be subject to the EU ETS. The [impact assessment](#) on which the proposal relies states that airlines are expected to pass on, to a large extent or even in full, compliance costs to customers. The price of intra-EU airline tickets is predicted to increase by €1.8 to €9 by 2020. Long-haul trips may see an additional cost of €8 to €40. The impact on cargo flights is unclear. However, one can easily imagine that cargo customers will bear the brunt of the compliance costs; they are analogues to a tax or fuel surcharge. All airlines benefit from passing on the costs rather than assuming them, as has been seen with the utilities sectors.

Under the Commission proposal airline carriers would be the entities responsible for compliance with the EU ETS, each of them falling under the competence of one Member State. In general, Member States would have to treat domestic aviation the same way as international aviation. The allowance allocation method would be harmonised Community-wide. Finally, by the end of 2008 the Commission will put forward a proposal addressing nitrogen oxide emission from aviation.

## Action items

The Commission's January Communications, "[Limiting Global Climate Change to 2 degrees Celsius: The way ahead for 2020 and beyond](#)" and "[An Energy Policy for Europe](#)" demand even more stringent policies, including a 20% reduction (as compared to 1990) in greenhouse gases by 2020, even though many Member States are struggling with their current target reductions for 2012. Industry must engage at both the national level and EU level in the on-going review and expansion of the EU ETS and, more broadly, the EU's climate change policy. Involvement should include, amongst other things, participation in consultations

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and provision of relevant data. Failure to participate may lead to future regulation which is unduly restrictive or impracticable.

### 3. NUTRITION AND HEALTH CLAIMS REGULATION COMES INTO FORCE

By [Craig Simpson](#)

#### Overview

[Regulation \(EC\) No 1924/2006](#) on nutrition and health claims made on foods ("the Regulation") entered into force on 19 January 2007 and will apply from 1 July 2007. The Regulation is without doubt the most controversial measure in the food arena in recent years. During its legislative passage, the Council and the Parliament adopted strongly opposing positions regarding the two most controversial aspects of the Regulation: (1) nutrient profiling; and (2) prior authorisation of new health claims, finally agreeing on a compromise which still presents a number of challenges for industry.

The Regulation sets out the circumstances in which food and drink, including food supplements, ("food") manufacturers are permitted to make health and nutrition claims on their products. It covers claims made in advertising and commercial communications as well as words, pictures or symbols featuring on product labelling. The Regulation establishes a transitional period until 31 July 2009 during which non-compliant foods already on the market or labelled at the date of application of the Regulation may continue to be marketed.

#### Nutrient profiling

The Regulation establishes that nutrition or health claims can only be made for a food where the content of certain nutrients including salt, fat, sugar and other substances (such as fibre) are below levels established in a nutrient profile for that food. The aim is to avoid nutrition or health claims masking the overall nutritional status of a "bad" food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet. An example

would be the claim "containing vitamin C" on a chocolate bar. This requirement is viewed by the Commission as a key element in fighting obesity (another key objective in EU food policy). As a concession to industry's concerns that profiling will discriminate against certain products, the Regulation contains an eleventh hour compromise provision that allows nutrition claims where only a single nutrient of the food exceeds the limit in the nutrient profile. However, this is subject to the condition that the statement "High content of [nutrient exceeding the nutrient profile]" appears with "equal prominence and in close proximity to the nutrition claim".

On the basis of scientific advice to be provided by the [European Food Safety Authority](#) ("EFSA"), the Commission must, by 19 January 2009, draw up nutrient profiles and conditions for use of claims relating to that profile through a comitology procedure (the "regulatory procedure"). (However, as noted in the [October edition of EU Analyst](#), the Regulation is among those where the Commission has proposed that the new "regulatory procedure with scrutiny" be applied in certain areas, including for the creation of nutrient profiles and conditions for the use of claims. The extent to which the new procedure applies is the subject of an ongoing dispute between the Commission and Parliament.)

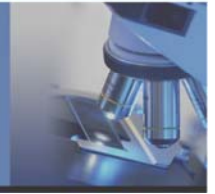
The Commission is required to consult with industry and consumer groups in setting the profiles. The Regulation allows for a transitional period of up to two years after adoption of nutrient profiles in which foods not complying with the relevant profile may continue to be marketed. EFSA's scientific work must be carried out within 12 months of entry into force of the Regulation and will focus on whether different profiles should be set for different categories, which nutrients need be controlled, calculation methods and appropriate reference quantities (for example, per 100g or per portion).

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## Prior authorisation of new health claims

The Regulation establishes two distinct categories of health claim:

- generally accepted and scientifically proven existing health claims (“Article 13 claims” or “permitted claims”) which are well understood by the average consumer; and
- new health claims.

Permitted claims in the following categories must appear on a positive list in order to be used (without prior authorisation):

- growth, development and functions of the body (such as, “good for bones”);
- psychological or behavioural functions (for example, “improves memory”);
- slimming (for example, “reduces calorie intake”); and
- reduction of hunger or reduction of available energy (in the case of energy-restricted diets for weight reduction).

EU Member States must provide the Commission with a list of such claims and supporting scientific evidence (provided by industry) by 31 January 2008. In consultation with EFSA, the Commission must adopt a positive list (through a comitology procedure) of permitted claims and their conditions for use based on the Member States’ lists by 31 January 2010.

The Regulation requires prior authorisation for new health claims. A “fast track” authorisation procedure will be used for inclusion of most new health claims on the Community positive list (“Article 13(5) claims”). Only two types of new health claims are subject to the full authorisation procedure: (1) reduction of disease risk claims (for example, “helps reduce risk of osteoporosis”); and (2) new claims referring to children's development or health. The timetable for the

full procedure is longer. However, both procedures require prior approval through an authorisation procedure involving submission of a dossier to the rapporteur Member State which is then sent to EFSA. EFSA has five months (subject to extension) from receipt of a valid application to issue a risk assessment prior to the Commission’s final decision.

The level of substantiation of such claims, the number of studies required and the nature of those studies currently remains unclear. Industry has pointed out that claims referring to children's development or health are not defined in the Regulation and that there is no transition period for such claims. EFSA has publicly expressed concern that it will lack resources to meet this timetable (particularly given recent threatened budgetary restrictions) if it receives a large number of applications at the same time.

## Other requirements

Other key requirements in the Regulation are set out below:

- Claims must not be misleading, give rise to doubt concerning the safety or nutritional value of other foods, nor suggest that appropriate quantities of nutrients cannot be gained from a balanced diet.
- Nutrition claims (such as “rich in vitamin C” or “fat free”) must comply with certain conditions guaranteeing that they are scientifically justified.
- Generally accepted scientific data must substantiate the beneficial nutritional or physiological effect claimed.
- A nutrient must be present in sufficient quantity in the food to have the effect claimed, in an amount likely to be consumed and in a form directly available to the body.
- The so-called “average consumer” must be able to understand the claim.

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- Health claims must be accompanied by information on how much of, or how often, the product has to be consumed to produce the beneficial effect.
- Mandatory nutrition labelling of “the Big 8” (energy value, protein, carbohydrate, sugars, fat, saturates, fibre and sodium) must accompany health claims.
- Health claims referring to general, non-specific well being (“helps your body to resist stress”) will be permitted only if accompanied by a more specific, positive-listed, health claim.
- Health claims making reference to rate/amount of weight loss, on drinks containing more than 1.2% alcohol by volume or which claim that health may be affected by not eating the food will be totally prohibited.
- Recommendations of doctors or health professionals or associations (such as “recommended by the British Heart Foundation”) which are neither regulated by Community law nor relevant national rules will be generally prohibited (with limited exceptions).
- A trade mark or brand name which may be construed as a claim (so called “name claims”, for example, “Vitalite”) will only be permitted without prior authorisation if accompanied by a related and scientifically justifiable nutrition or health claim valid under the Regulation. There is a transitional period (until 19 January 2022) during which products that bore name claims before 1 January 2005, but which would constitute prohibited claims under the Claims Regulation, may continue to be marketed in the same manner.
- A claim that the risk of disease is reduced must be accompanied by a clarificatory statement that altering one of multiple risk factors may or may not have a beneficial effect.
- Applicants for authorisation can in certain circumstances benefit from a five year protection period from information in their dossiers being relied on by subsequent applicants.
- Generic (apparently innocuous) descriptors such as “cough drops”, “digestives” or “aperitifs” traditionally used to indicate a particular class of foods but “which could imply an effect on human health” must comply with the Regulation. However, a provision in the text permits adoption of derogations for specific descriptors authorised via a comitology procedure.

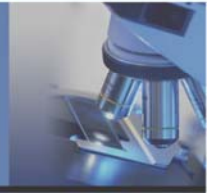
## Next steps

Member State competent authorities have already begun the process of collating the list of permitted health claims intended for the Commission’s positive list. National food authorities are encouraging food manufacturers to begin the submission of these claims as soon as possible to ensure manufacturers have sufficient time to gather the supporting scientific evidence before the deadline of 31 January 2008. Despite its own misgivings about the short time frame and budgetary pressures, EFSA is gearing up to provide the Commission with the scientific advice it needs to establish nutrient profiles. The precise terms of EFSA’s formal mandate from the European Commission remain unclear but it seems that the Commission and Member States will propose a request (a range of questions) on nutrient profiles to which the EFSA [NDA Panel](#) will respond with scientific advice.

## Action items

Industry must review which new health claims may require approval. EFSA has stated that it will consult on draft guidance on submitting a dossier on disease risk reduction claims and children’s health and development claims in the first half of 2007 and is urging companies to wait and see the guidance before submitting claims dossiers. Meanwhile, food manufacturers remain in regulatory limbo regarding which claims will:

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- be allowed under nutrient profiling,
- appear on the positive lists of generally accepted claims; and
- require authorisation.

Food manufacturers will need to ensure that they defend their interests by participating effectively in the forthcoming Commission consultations regarding nutrient profiles. They will also have to consider carefully how best to protect their continued ability to market their products. In some cases, they will need to consider whether current claims (particularly generic or name claims) are of sufficient marketing importance to warrant either reformulation of the product to satisfy the profile or an application for authorisation of the claim. As in other areas of life science (and environmental) regulation which include authorisation procedures, careful formulation of the authorisation dossier, including measures to protect proprietary data, will be essential.

To review previous versions of the EU Analyst, please check [here](#).

If you have any questions concerning this briefing, please contact Darren Abrahams ([dabrahams@steptoe.com](mailto:dabrahams@steptoe.com)).

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