A PERIODIC REPORT FROM STEPTOE & JOHNSON LLP

EU Analyst: Environment & Life Sciences

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CONTENTS

1. NEW "COMITOLOGY" DECISION MAKING PROCEDURE

By Darren Abrahams

Overview

Key decisions on EU environment and life sciences regulation are taken behind closed doors. "Comitology" committees authorise products (e.g. active substances in pesticides and biocides, and GMOs) and make minor, but commercially significant, amendments to legislation (e.g. exemptions to the RoHS and End of Life Vehicles Directives). The rules by which these committees operate have been substantially amended by the addition of a new "regulatory procedure with scrutiny". This will affect current environment and life sciences regulation and future legislative initiatives.

What is comitology?

"Comitology" is the umbrella term used for the different procedures by which committees (made up of EU Member States, chaired by the European Commission) exercise delegated powers to make key decisions in a wide range of policy areas including the environment, agriculture, transport and health and consumer protection. Last year, 32 of the 250 committees in operation worked solely on environmental regulation, whilst 15 committees worked on health and consumer protection. They produced 47 environmental and 303 health and consumer protection measures.

Main features of the new "regulatory procedure with scrutiny"

The aim of the new procedure (explained in the diagram at the end of this report) is to increase democratic scrutiny of comitology decisions. This responds to complaints by the European Parliament, over many years, that it was not sufficiently involved in this important process.

Firstly, the Parliament has been given an increased opportunity to oppose (and thereby veto) the adoption of proposed measures. It can do this where the draft measures: (i) exceed the implementing powers provided for in the basic instrument (a directive or regulation); (ii) are not compatible with the aim or content of the basic instrument; or (iii) do not respect the principles of subsidiarity or proportionality. These three grounds for opposition are drafted in wide terms, providing the Parliament with ample scope to make its voice heard. Over and above this, the Parliament retains the ability to bring legal action before the European Court of Justice challenging a comitology decision (as it has done on two occasions in the past year).

Secondly, where a proposed measure is vetoed the Commission does not have the option to resubmit it without amendment. Its only alternatives are either to submit an amended draft measure or to make a proposal for legislation pursuant to the EC Treaty (a more onerous undertaking). The absence of this option (which exists under the earlier "regulatory procedure", one of the four other comitology procedures) removes a political weapon from the Commission's armory.

Whom does this affect?

Ten current environment and life sciences laws will be amended as a matter of urgency in order to substitute the new procedure where they currently apply comitology:

- Directive 2002/96/EC on waste electrical and electronic equipment ("WEEE")
- Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("RoHS")
- Directive 98/8/EC concerning the placing of biocidal products on the market
- Directive 2000/60/EC establishing a framework for Community action in the field of water policy
- Directive 2000/53/EC on end of life vehicles
- Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms
- Directive 2001/83/EC on the Community code relating to medicinal products for human use
- Regulation (EC) No 1829/2003 on genetically modified food and feed
- Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin
- Regulation (not yet published in the *EU Official Journal*) on nutrition and health claims made on foods

Next steps

In addition to amending the above-mentioned measures, the Commission will screen all other existing legislation and bring forward proposals to adapt it (so as to apply the "regulatory procedure with scrutiny" where applicable) by the end of 2007. Key dossiers which might be considered as good candidates for this new procedure include the revision of the existing directives on medical devices and plant protection products.

2. NEW WASTE SHIPMENT RULES

By Laura Atlee

Overview

Regulation (EC) No 1013/2006 on shipments of waste ("the new Regulation") will apply in all EU Member States from 12 July 2007. It replaces Regulation (EC) 259/93 ("the old Regulation"). The new Regulation applies (with certain exceptions) to shipments of waste:

- *between Member States*, within the European Community ("Community") or with *transit through third countries*
- *imported* into the Community from third countries
- *exported* from the Community to third countries
- *in transit through the Community*, on the way from and to third countries

The new Regulation aims to simplify and consolidate the existing waste shipment regime but it is far from clear that this has been achieved. There are a number of differences between the old Regulation and the new Regulation, several of which are highlighted below.

"Simplification" of control regimes

Under the new Regulation there are only two procedures/control regimes which apply to waste shipments - "prior written notification and consent" and "general information requirements". Which of these two procedures applies depends on: (i) the purpose for which the shipment is made (disposal or recovery), (ii) the classification of the waste, and (iii) the route which the waste takes.

Waste that was previously classified under the "Red List" is now found under various sections of Annex V (on wastes subject to various prohibitions) of the new Regulation. The only exception to this is for "Ceramic-based fibers of physico-chemical characteristics similar to those of asbestos", which is now found on the

"Amber List of Wastes". The new Regulation no longer contains a separate "Red List".

The diagram at the end of this report explains how to determine which of the two procedures applies for shipments *within* the Community (with or without transit through third countries). The following aspects are noteworthy: notification and movement forms must be submitted for prior written notification and consent (see top left column to diagram). These are found in Annexes IA and IB respectively. Annex II is a list of information and documentation that must be supplied on, or annexed to, these forms. Additionally, a contract between the notifier and consignee and a financial guarantee or equivalent insurance must be prepared. If only general information requirements are applicable (see bottom left column to diagram), the person under the jurisdiction of the country of *dispatch* who arranges the shipment of the waste must ensure that the form provided in Annex VII accompanies the shipment. The form requires "effective written contractual obligations [to] have been entered into with the consignee" and the new Regulation specifies the obligations that must be contained in the contract.

In the old Regulation (in instances of certain wastes being shipped, for disposal or recovery, from one Member State to another and/or passing in transit through one or more additional Member States), the notifier was required to apply for authorisation to the authorities of *destination*. The notifier was also required to send a copy of the application to the authorities of the States of dispatch, transit and of the consignee (unless national legislation permitted otherwise). In the new Regulation, the notifier must apply for authoritisation through the competent authorities of *dispatch*. The authorities of dispatch retain a copy of the application and transmit the notification to the authorities of destination and send copies to any authorities of transit.

Contractual requirements

With respect to the mandatory contract between the consignee and the notifier, the old Regulation listed information that could be included in the contract. It also required three conditions: (1) the notifier had to take back waste if the shipment had not been completed as planned or was effected in violation of the Regulation; (2) the consignee was required to provide, within 180 days or less following receipt of the waste, a certificate to the notifier stating that the waste had been disposed of/recovered in an environmentally sound manner; and (3) if the waste was being transported for recovery and retransferred to another Member State or third country, the consignee had to notifty the initial country of dispatch. The new Regulation provides for the following contractual obligations:

- The *notifier* must take back the waste if the shipment, recovery, or disposal has not been completed as intended or has been effected as an illegal shipment and is the responsibility of the notifier.

- The *consignee* must recover/dispose of the waste if it has been effected as an illegal shipment and is the responsibility of the consignee.

- The *facility of (non-interim) recovery* or disposal must send a certificate of completion to the notifier and authorities concerned *no later than 30 days after completion* of the recovery/disposal, and no later than *one calendar year* or shorter if required by authorities, following receipt of the waste.

Additional provisions must be included in the contract if the waste is shipped for interim recovery/disposal.

Action items

In conclusion, the new Regulation changes, among other things, the applicable procedures, the notifier's and consignee's obligations, and the timeframes within which authorities must make decisions. Therefore, entities engaged in any aspect of waste shipment, particularly those that are involved with shipments that go beyond their national jurisdictions, should re-evaluate their procedures and contracts.

3. DOOR OPEN TO INCREASED LIABILITY FOR FOOD DISTRIBUTORS

By Darren Abrahams & Craig Simpson

Overview

On 12 September, Advocate General Stix-Hackl delivered her long awaited opinion in European Court of Justice ("ECJ") case C-315/05, *Lidl Italia Srl v Comune di Arcole (VR)*. The case concerns the extent of liability of "food operators" and, specifically, whether (and in what circumstances) distributors of food (such as supermarkets) may be deemed "food operators" and therefore be held liable for breaches of food labelling, presentation and advertising laws. The demarcation of liabilities between food manufacturer and distributor has clear consequences for the entire food chain. An Italian court has referred these questions of law to the ECJ for its preliminary ruling.

Facts of the case

A fine was imposed on Lidl Italia ("Lidl") - a food retailer and distributor - when national enforcement authorities discovered that the label of a pre-packaged foodstuff (a herbal liqueur) it was selling bore a label which did not accurately reflect its true alcohol content. Directive 2000/13/EC on labelling, presentation and advertising of foodstuffs defines "pre-packaged foodstuff" as "any single item for presentation as such to the ultimate consumer and to mass caterers, consisting of a foodstuff and the packaging into which it was put before being offered for sale, whether such packaging encloses the foodstuff completely or only partially, but in any case *in such a way that the contents cannot be altered without opening or changing the packaging*" (Article 1(3)). Directive 2000/13/EC also provides that labelling must not "mislead the purchaser to a material degree, particularly: as to the…composition…" (Article 2(1)) and applies, amongst other things, to beverages containing more than 1.2% by volume of alcohol. A margin of error in the statement of alcohol content of 0.3% is permitted by Directive 87/250/EEC. In the case before the Italian court, it was claimed that this tolerance level had been exceeded.

Key issues

Lidl challenged the decision that it had breached the aforementioned rules on labelling, arguing that a distributor cannot be held responsible for the content and labelling of products which it does not manufacture. The Italian court referred two questions to the ECJ:

- Must Directive 2000/13/EC be interpreted as meaning that the obligations regarding pre-packaged foodstuffs - and in particular those in Articles 2 (concerning misleading labelling), 3 (concerning alcoholic beverages) and 12 (concerning tolerance levels for volume content) - are imposed *only* on the producer of the pre-packaged food product?

- *If* those obligations are only imposed on the producer, must Articles 2, 3 and 12 be interpreted as *precluding the possibility that a mere distributor* of a pre-packaged foodstuff, selling products produced by a trader in another Member State, *may be held liable* for an infringement relating to alcohol content labelling and may thus be penalised, even if the distributor simply markets the foodstuff in the form in which it is delivered by the producer of the food product itself?

The Advocate-General's opinion

Advocate-General Stix-Hackl acknowledges that the addressee of the obligations in article 2 and 3 is not identified, but nonetheless concludes that they are not imposed exclusively on producers. Such a limitation (to producers only) would, in her view, be contrary to "the spirit and the purpose" of the directive which is aimed at informing and protecting the consumer. In view of the "ever closer and increasingly complex relationship between manufacturers, producers and distributors, responsibility ought in principle to be joint rather than individual".

However, the Advocate-General does not conclude that this *automatically* renders all parties involved in distribution as liable for labelling errors. In order for a party to be liable, it "should be in a position to verify

that the particulars on the label of the product are substantively accurate". Whilst the distributor of a product is not usually in a position to supervise the product manufacturing process, "it is not entirely inconceivable that, in certain cases, the distributor may be able to undertake such supervision". For example, a distributor involved in the pre-packaging of products could be held responsible. The Commission argued before the ECJ that distributors (such as large supermarket chains) have sufficient power to impose on manufacturers rules or quality criteria relating to the manufacture of foodstuffs. These criteria could be enforced by means of inspection programmes or regular checks; distributors may therefore be liable for non-adherence to these criteria.

Next steps

The ECJ should hand down its judgment during 2007. The ECJ is not required to follow the Advocate-General, but if it were to do so, this would place a potentially greater burden of responsibility on food distributors. The question of whether a party is *actually* able to verify the particulars of a food label would have to be examined on a case by case basis and different enforcing authorities might well take opposing views on what constitutes the required level of control. This shifting of responsibility may also strain contractual relationships between producer and distributor as each party seeks to minimise its potential exposure to risk.

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

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<table>
<tr><th colspan="4">NEW WASTE SHIPMENT RULES</th></tr>
<tr><th></th><th>Disposal</th><th>Recovery</th><th></th></tr>
<tr><td colspan="4">Within the Community, with or without transit through third countries</td></tr>
<tr><td rowspan="2">Prior Written Notification and Consent</td><td>ALL waste</td><td>1) amber listed waste, 2) certain green listed waste that requires prior written notification and consent (Annex IVA), 3) waste/mixtures, not classified under one single entry in a) the green listed waste, b) the list of additional green listed waste awaiting inclusion in the relevant annexes of the Basel Convention or OECD Decision, c) the amber listed waste, or d) certain green listed waste that requires prior written notification and consent (Annex IVA) (unless the mixture falls under the list of “mixtures of two or more green listed wastes classified as a single entry”)</td><td rowspan="4">From the start of the shipment to the receipt in a recovery or disposal facility, waste, as specified on the notification document or referenced in the general information document (Annex VII form), must NOT BE MIXED with other waste.</td></tr>
<tr><td colspan="2">Mixed municipal waste from private households is treated like waste for disposal</td></tr>
<tr><td rowspan="3">General Information Requirements (Art. 18)</td><td></td><td>If the waste is more than 20 kg and: 1) green listed waste, 2) additional green listed waste awaiting inclusion in the relevant annexes to the Basel Convention or OECD Decision, 3) mixtures of two or more wastes on the green waste list, but not classified under one entry on the list, IF the composition of the mixture does not impair environmentally sound recovery and the mixture is listed on the list of mixtures of two or more green list wastes and not classified as a single entry.</td></tr>
<tr><td></td><td>Green listed waste that displays the following hazardous characteristics may (after amendment) be treated like amber listed waste: H1-explosive, H2-oxidizing, H3-highly flammable, H3-B-flammable, H4-irritant H5-harmful, H6-toxic, H7-carcinogenic, H8-corrosive, H9-infectious, H10-teratogenic, H11-mutagenic,H12-substances/preparations that release (very) toxic gases in contact with water, air, or an acid, , H13-substances/preparations capable by any means, after disposal, of yielding another substance (e.g. a leachate), H14-ecotoxic.</td></tr>
<tr><td colspan="2">Waste explicitly destined for laboratory analysis for physical/chemical characteristics or to determine its suitability for recovery or disposal operations. It may not exceed 25 kg.</td></tr>
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COMITOLOGY: REGULATORY PROCEDURE WITH SCRUTINY[1]

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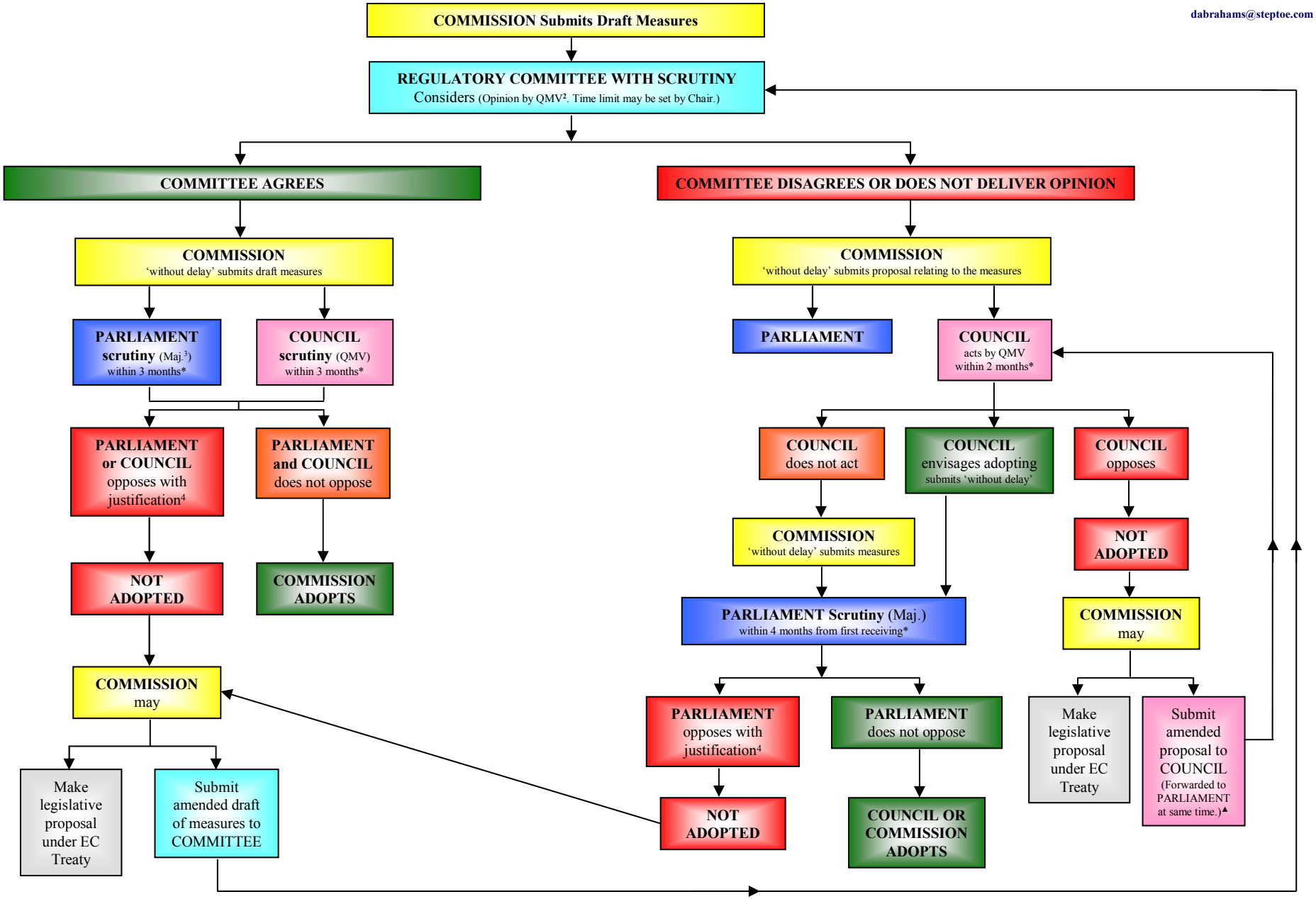

1. Council Decision 2006/512/EC of 17 July 2006.
2. Qualified Majority Voting under Art. 205(2) EC Treaty. Committee members may also invoke Article 205(4). It is not clear if this applies in the Council.
3. Majority of its component members.
4. Justification: draft measures (i) exceed implementing powers provided for in the basic instrument; (ii) are not compatible with the aim/content of the basic instrument; or (iii) do not respect subsidiarity or proportionality.
* May be extended by 1 month if complex or curtailed if efficient. An abbreviated procedure may be provided for in situations of imperative urgency.
▲This is not expressly stated but is implicit.