



EPHA Briefing for members

Subject	An introduction to co-regulation and self-regulation in the EU
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Background

Recent years have seen a change in the nature of regulatory activity at EU level. There has been a continuing shift away from legally binding instruments (i.e. Regulations and Directives laid down by the EU institutions) to **alternative regulatory methods**, such as co-regulation and self-regulation by the social and economic actors concerned.

The emergence of “alternative” methods of regulation has been motivated by the paradigm of “**New Public Management**” (NPM). The main idea behind NPM is to decentralise traditional hierarchical bureaucracies and to utilise civil society actors in implementing and managing policies. That is expected to reduce costs and increase efficiency in the production of public services.

Initiatives for co-regulation and self-regulation can take many forms: voluntary agreements, codes of conduct, charters, guidelines and harmonised standards etc. They have developed in a number of fields, most notably technical standards, professional rules, social dialogue and the environment,

A legal framework and definitions of the concepts of self-regulation and co-regulation was introduced at EU level by the *Inter-Institutional Agreement on Better Law-making* (IIA) concluded between the Parliament, the Council and the Commission in December 2003. However, as noted by the forthcoming EESC report¹, “the concept remains little understood, even in social and economic circles”.

Legal framework

The IIA recalls that, under the principles of subsidiarity and proportionality, the *Community is obliged to legislate only where it is necessary* and recognises the need to use, in suitable cases or where the Treaty does not specifically require the use of a legal instrument, alternative regulation mechanisms.

At the same time, it specifies the conditions under which the alternatives may be applied. Thus co-regulation and self-regulation:

- must be consistent with Community law, represent added value for the general interest, meet the criteria of transparency (in particular the publishing of agreements) and representativeness of the parties involved.
- cannot be used where fundamental rights or important political options are at stake or in situations where the rules must be applied in a uniform fashion in all Member States; cannot affect the principles of competition or the unity of the internal market.

CO-REGULATION

Co-regulation is designed to focus EU regulatory work on the “essential elements” of the legislation and draw on the experience of the parties concerned to fill in the details. It is a top-down approach, conceived essentially as a means of implementation.

Definition

The IIA defines co-regulation as a “*mechanism whereby a Community legislative act entrusts the attainment of the objectives defined by the legislative authority to parties which are recognised in the field* (such as economic operators, the social partners, non-governmental

¹ Preliminary Draft Information Report of the Section for the Single Market, Production and Consumption on the Current state of co-regulation and self-regulation in the Single Market, Rapporteur: Mr Vever, INT/204 -R/CESE 1182/2004.

organisations, or associations).”

It states that this mechanism is intended to “*enable the legislation to be adapted to the problems and sectors concerned, to reduce the legislative burden by concentrating on essential aspects and to draw on the experience of the parties concerned.*”

How does it work:

- The legislator establishes the essential aspects of the legislation (the objectives to achieve) and indicates the possible extent of co-regulation.
- The parties concerned conclude an agreement that specify the details of legislation.
- The Commission verifies whether a draft agreement complies with Community law (and, in particular, with the basic legislative act) and notifies the Parliament and the Council.
- In some, not very precisely defined cases (*at the request of inter alia the European Parliament or of the Council, on a case-by-case basis and depending on the subject*) the Parliament and the Council may have the option to suggest amendments to the draft agreements (if they consider that it does not meet the objectives laid down in the basic legislative act) or object to its entry into force and, possibly, ask the Commission to submit a proposal for a legislative act.
- In cases where using co-regulation mechanism has not produced the expected results (e.g. the parties concerned do not reach an agreement), the Commission reserves the right to make a traditional legislative proposal to the legislator.

Examples:

The procedure, as defined in the IIA, has not been employed yet. However, a number of regulatory mechanisms used at EU level bear strong features of co-regulation. The best example is the so-called "**new approach**" to **product standardisation** introduced in 1985 in the area of technical harmonization, whereby the European legislator establishes the essential health and safety requirements of harmonisation and the detailed specifications are then adopted by standards bodies approved at EU level.

SELF-REGULATION

In contrast to co-regulation, **self-regulation** represents a more bottom-up regulatory approach and is initiated by the stakeholders themselves. However, the European institutions can decide to act in support of a given self-regulation process and even to make it compulsory by making it a binding legal instrument.

Definition

Self-regulation is defined by the Interinstitutional Agreement as *the possibility for economic operators, the social partners, non-governmental organisations or associations to adopt amongst*

themselves and for themselves common guidelines at European level (particularly codes of practice or sectoral agreements).

As a general rule, this type of voluntary initiative does not imply that the Institutions have adopted any particular stance, in particular where such initiatives are undertaken in areas which are not covered by the Treaties or in which the Union has not hitherto legislated.

How does it work:

- The Commission notifies the Parliament and the Council of the self-regulation practices which it regards, on the one hand, as contributing to the attainment of the EC Treaty objectives and as being compatible with its provisions and, on the other, as being satisfactory in terms of the representativeness of the parties concerned, sectoral and geographical cover and the added value of the commitments given.
- It can nonetheless issue a proposal for a legislative act, in particular at the request of the Parliament or the Council or in the case when self-regulation practices are not observed.

Examples:

Self-regulation is well established in areas such as professional rules and standards for print, radio and broadcast media and for the advertising industry. However, as in the case of co-regulation, it has not yet been used within the framework provided for by Inter-Institutional Agreement on better law-making.

Development of European co-regulation and self-regulation

A number of alternatives to traditional regulatory instruments have been in use in the EU for some time. These include technical standardisation, social dialogue, and business self-regulation.

1. TECHNICAL STANDARDISATION

The so-called “**new approach**” to **product standardization**, introduced by a Council Resolution of 1985², has resulted in a new legislative procedure based on a clear separation of responsibilities between the European legislator and the stakeholders. It was conceived as an option for focusing EU regulatory work on the essential elements of the legislation and drawing on the experience of the parties concerned to fill in the details.

The EU Directives are thus confined to the “essential requirements” of harmonisation (mainly

² Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards (85/C 136/01), [http://www.eotc.be/newapproach/EC_Guide/Download_Docs/Council Decision - New Approach to Technical Harmonization and Standards. \(85-C136-01\).pdf](http://www.eotc.be/newapproach/EC_Guide/Download_Docs/Council%20Decision%20-%20New%20Approach%20to%20Technical%20Harmonization%20and%20Standards.%20(85-C136-01).pdf)

linked to considerations of safety, health, the environment and consumer protection), whereas the corresponding **technical specifications are referred to the European Committees**, of which national standardisation or certification bodies are members, as are the professions directly concerned by these specifications. Products complying with the standards developed by these bodies benefit from the presumption of conformity that all legal requirements are satisfied.

Several thousand European standards have thus been adopted by the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC), and the European Telecommunications Standards Institute (ETSI).

In the area of healthcare, CEN Healthcare Sector Forum (CHeF) develops European Standards on the basis of **three EU directives on medical devices**:

- Medical Devices Directive **(93/42/EEC)**³,
- Directive on Active and Implantable Medical Devices Directive **(90/385/EEC)**⁴ and
- Directive on In Vitro Diagnostic Medical Devices **(98/79/EC)**⁵

Likewise, CEN has produced several hundred European Standards on foodstuffs (mainly for methods of sampling and analysis) and occupational health and safety (in the areas such as machinery, pressure equipment, personal protective equipment and transport).

On the whole, the “new approach” regulatory framework has worked well. It has to be noted, however, that compliance with harmonised standards remains voluntary, and manufacturers are free to choose any other technical solution that provides compliance with the “essential requirements” of EU legislation.

However, there have been calls for more detailed EU legislation in order to provide better protection of health and safety. Recently, for instance, a number of European patients and medical associations called for EU action to regulate the reprocessing of single use medical devices in the interests of public health and the safety of patients and healthcare workers⁶

³ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31993L0042&model=guichett

⁴ Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31990L0385&model=guichett

⁵ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31998L0079&model=guichett

⁶ [http://www.eucomed.be/docs/Final Revised Manifesto December 2 with logo.pdf](http://www.eucomed.be/docs/Final%20Revised%20Manifesto%20December%202002%20with%20logo.pdf)

2. EUROPEAN SOCIAL DIALOGUE

European social dialogue between the two sides of industry arose in the mid-1980s as part of a drive by Commission President at the time, Jacques Delors, to build a social aspect to the European internal market. The European Commission invited EU employer organisations (UNICE and CEEP) and trade unions (ETUC) to engage in labour market dialogue as “social partners” and a number of agreements between them have arisen as a result.

In 1992, the Maastricht Treaty introduced a more institutionalized form of this dialogue, giving employer organizations and trade unions the right to be consulted on the content and direction of social policy, and even to draft EU labour market legislation themselves.

The current **Article 138 of EC Treaty** envisages a **mandatory two-stage consultation of the European social partners** in all matters of EU social policy. First, when submitting proposal in the area of social policy, the Commission is obliged to consult employer and trade union organisations on the possible **direction** of Community action. Second, if after this first stage of consultation the Commission considers community action advisable, it must consult the social partners on the **content** of the envisaged proposal.⁷

At the second stage of consultation (on the contents of the proposal), the European social partners may inform the Commission of their wish to initiate negotiations (**article 139**). In this case, the ordinary legislative procedure is suspended and replaced by **social partner bargaining**.

The agreements reached in such negotiations are legally binding and can be implemented in two ways. Social partners can decide to implement their agreement “in accordance with the procedures and practices specific to management and labour and the Member States”, i.e. at a national level. Alternatively, they can request that their agreement be implemented at a European level by means of a Council Decision (in practice so far by Council Directives – see below) and monitored by the Commission. For key steps of European social dialogue procedure, see Annex 1.

Although a breakthrough in the sense that it endows private interests with law-making capacity, the significance of European social dialogue should not be exaggerated. The concrete results of this process do not match its strong legal basis and potential important impact.

Quantitatively, negotiations between UNICE, CEEP and UEAPME on the one hand and ETUC on the other, have resulted in just **five cross-industry framework agreements**. Three of them - on parental leave (1996), part-time work (1997) and fixed-term work (1999) - were transformed into EU Directives, whereas the other two - on telework (2002) and work-related stress (2004) - form the object of a voluntary agreement to be put into force by the national employer and trade union

⁷ According to Commission policy guidelines, the time limit for each consultation period is six weeks, although the Commission may extend this deadline.

organizations. Three agreements were also concluded and turned into community legislation at the sectoral level. They concern working time for the maritime and civil aviation sector and the working conditions in railway sector.

On other occasions, agreements have either broken down or employers have refused Commission's invitation to enter into negotiations.⁸

Moreover, those agreements that have been reached were only of **limited impact**. For instance, the 1996 parental leave directive only advanced protection of workers in three Member States, other countries already having more stringent legislation in place.⁹ Likewise, in the case of part-time work and fixed contracts, the actual content of the agreements is considered to be quite modest.

Another problem is legitimacy. Social partner bargaining, which may ultimately culminate in EU directives, leaves out the Parliament, the only EU institution that is directly elected and with a democratic mandate. It also does not allow the Council (Member States) to make any changes to the negotiated text. This raises a question as to the legitimacy and democratic accountability of a situation in which EU law is drafted by a small number of trade unions and employers.

3. BUSINESS SELF-REGULATION

In recent years, self-regulation has also developed in certain business sectors. It has taken various forms, such as codes of conduct, declarations, charters, agreements, rules, standards and labels.

Industry is, in general, very positive about self-regulation and co-regulation mechanisms, presenting them as a means to reduce over-regulation in the EU. A newly formed *Alliance for a Competitive European Industry*, which brings together twelve EU business associations including food (CIAA), chemicals (CEFIC), car and oil industries, has recently called on EU institutions to give more attention to “alternative policy options” including “no action”. According to the alliance, the regulator should make an “informed decision on the policy option which would be most appropriate to achieve the objectives, thereby eventually avoiding resorting to regulation when other options could be more effective”.¹⁰

It is interesting to note that **self-regulation is most commonly adopted by industries under threat of legislation** or other forms of binding action by public authorities. A good example is the case of the so-called “pedestrian-friendly” car fronts. Following announcements from EU Transport Commissioner that the Commission was planning to introduce legislative proposal on safer car fronts to protect the lives of pedestrians and cyclists, the car industry engaged in intensive lobbying, urging the Commission to leave the issue to industry self-regulation. The result was a voluntary

⁸ J. Greenwood, *Interest Representation in the EU* (Basingstoke: Palgrave Macmillan, 2003) pp.68-9.

⁹ *Ibidem*, p. 169., 35-7.

¹⁰ http://www.cefic.be/files/Publications/Position_Paper_Impact_Assessment.pdf

agreement between European, Japanese and Korean Automobile Manufacturers Associations (ACEA, JAMA and KAMA) reached in 2001. Transport safety and consumer NGOs have criticised the agreement as very weak, pointing out that it would lead to 50% less protection than the proposed Directive.¹¹

Corporate Social Responsibility (CSR)

Most of business self-regulation initiatives have been developed within the framework of the **corporate social responsibility** (CSR), a term used to describe industry's commitment to **improve corporate performance in relation to social, environmental and ethical criteria**. CSR-related instruments are usually based on existing agreements, such as the guidelines and legislation of the Organisation of Economic Co-operation and Development (OECD) and the International Labour Organisation (ILO) and human rights treaties, to which the companies voluntarily agree to adhere.

To "facilitate further development towards a framework for CSR practice at European level based on, and complementary to, already existing CSR initiatives in the business community and the Member States", the Commission issued a Green Paper on a European framework for Corporate Social Responsibility¹² in 2001, which was followed by a Communication in July 2002¹³. The Communication was then subject to stakeholder consultation in the framework of the **Multi Stakeholder Forum on CSR**¹⁴, launched in October 2002.

The forum was co-ordinated by the European Commission DG Social Affairs and DG Enterprise and comprised representatives of four 'families' of stakeholders: employers organisations, business groups, trade unions and NGOs. The debate among the stakeholders focused mainly on whether a **voluntary or mandatory approach to CSR** would be the right one.

Industry emphasised the voluntary basis of CSR, to allow each company to find the methods suitable for its culture and needs. On the other hand, many NGOs and think-tanks were explicitly against the present voluntary approach to CSR. They claimed that social and environmental reporting is not efficient and credible without any standardised methods or independent monitoring.

The Forum presented its final report in June 2004 and it will now feed into a follow-up Communication by the Commission due to come out early next year. To the disappointment of many NGOs, Forum's conclusions do not envisage any mechanisms of mandatory regulation in the field of CSR. In response, NGOs from the social, environment, human rights, development, and

¹¹ http://www.etsc.be/documents/pre_10july01.htm

¹² Green Paper: Promoting a European framework for Corporate Social Responsibility, COM (2001) 366, http://europa.eu.int/prelex/detail_dossier_real.cfm?CL=en&DosId=166520

¹³ Communication concerning Corporate Social Responsibility: A business contribution to Sustainable Development [FR] [DE] (2 July 2002), http://europa.eu.int/comm/employment_social/soc-dial/csr/csr2002_en.pdf, COM (2002) 347

¹⁴ http://forum.europa.eu.int/irc/empl/csr_eu_multi_stakeholder_forum/info/data/en/csr_ems_forum.htm

consumer sector released an open letter demanding binding legal measures to ensure the accountability of companies:

“Taken together the recommendations, if they are fully implemented by the relevant actors, will help to generate a significant advance. For that to happen, however, it will be necessary to develop them into a proper framework (...) and ultimately to ensure accountability by *all* companies (...) Voluntary initiatives are not enough to reverse the unsustainable impacts of corporate activities (...) Only binding legal measures will establish a general incentive for responsible corporate behaviour”.¹⁵

This implies **mandatory social and environmental reporting** for all EU companies over a certain size based on a set of common standards, and an independent monitoring/verification system.

The example of advertising self-regulation

The prime example of business self-regulation and corporate social responsibility is self-regulation in the advertising sector. It is found, in varying forms, in most European countries.

Self-regulatory systems are based on voluntary codes of conduct drawn up by the advertisers, agencies and media, and are applied by self-regulatory bodies or committees set up for this purpose and funded by the advertising industry itself.

According to the European Advertising Standards Alliance (EASA), self-regulation in the advertising sector stems from the recognition that “advertising should comply to a set of ethical rules, namely that it should be legal, decent, honest and truthful, and prepared with a sense of social responsibility to the consumer and society as a whole”.¹⁶

Despite industry’s claims that self regulation on advertising is effective, many NGOs have concerns that voluntary codes are often not sufficient to restrain unacceptable practices. Particularly because self-regulation is most commonly adopted by industries under threat of government regulation. This is particularly the case with regard to a commercial sector that involves products which can be harmful to health, such as tobacco, alcohol and processed food. When faced with the threat of government restrictions, particularly on marketing practices, the tobacco, alcohol and food industry have always argued for voluntary codes of conduct.

In the view of many health experts these codes tend towards under-regulation and under-enforcement and are often used for public relations purposes. The main problems with self-regulated advertising codes concern:

¹⁵ <http://www.socialplatform.org/code/en/camp.asp?Page=308>

¹⁶ <http://www.easa-alliance.org>

The nature of the codes: Most self-regulatory codes are largely irrelevant to the way alcohol, tobacco and food advertising actually works. They deal with the content rather than the volume of advertising even though the attitudes and behaviour of the public are likely to be affected by the sheer number and repetition of advertisements as well as their content.

Moreover, the wording of the codes tends to be vague and general. It leaves wide scope for interpretation, providing both incentive and opportunity for advertisers to find ways of pushing the rules to the limits or circumventing them.

Violations of the code: A recent analysis of self-regulation of alcohol marketing in the Netherlands¹⁷ concluded that violations of the code were committed regularly even by the big advertisers. It also detected an increasing number of advertisement which met the letter but arguably not the spirit of the code. A Spanish study of tobacco advertisements¹⁸ found that although the self-regulation code of the Spanish Tobacco Association was formally respected, the advertisements displayed subtleties that allowed the industry to get around the code. For instance, most advertisements refrained from claiming therapeutic properties of tobacco (which is forbidden under the code) but at the same time linked smoking with social success and leisure. Likewise, although children were not used as models, many advertisements depicted famous people (mainly pilots and artists) and iconic personages (Joe Camel and Marlboro Man) that are particularly attractive to the young.

Enforcement and Sanctions: Most advertising code committees only provide recommendations and breaches of the codes do not carry a penalty. Even if this is the case, sanction mechanisms can prove difficult to implement, overly complex and ineffective. In the analysis conducted in the Netherlands it was observed that, even if breaches occurred repeatedly, the Advertising Code Committee had never imposed a fine despite several requests from National Foundation for Alcohol Prevention. On average, it takes a few months before the advertising Code Committee rules on a complaint about a commercial or advertisement. In most cases, the campaign concerned has long been completed when the Committee gives its verdict.

All this points to the limitations of advertising codes of conduct. In the view of NGOs working on alcohol and tobacco issues, industry is not capable of policing itself. One cannot “ask a bird to clip its own wings”. On the other hand, legal measures, such as comprehensive advertisement bans and price increases, have proved to be effective on consumption patterns of tobacco and alcohol¹⁹. In such cases the legislator’s intervention seems both justified and necessary.

¹⁷ *Don't ask a bird to clip its own wings* – Analysis of self regulation of alcohol marketing in the Netherlands – STAP – National Foundation for Alcohol Prevention.

¹⁸ Martin M, Quiles Mdel C, Lopez C., “Los sistemas de autorregulación como mecanismos de control de la publicidad de tabaco: evaluación mediante análisis empírico”, in: *Gaceta Sanitaria*, 2004; 18(5), pp. 366 – 373.

<http://db.doyma.es/cgi->

[bin/wdbcgi.exe/doyma/mrevista.pubmed_full?inctrl=05ZI0108&rev=138&vol=18&num=5&pag=366](http://db.doyma.es/cgi-bin/wdbcgi.exe/doyma/mrevista.pubmed_full?inctrl=05ZI0108&rev=138&vol=18&num=5&pag=366)

¹⁹ World Bank, “Curbing the Epidemic : Governments and the Economics of Tobacco Control”, 1999, <http://www1.worldbank.org/tobacco/>

Speaking at the World Federation of Advertisers, Health and Consumer Protection Commissioner David Byrne stated that “**advertising codes cannot replace the need for a legislative framework**. The presence of a regulatory back-stop gives code-owners the power to promote compliance, and ensures that action can always be taken where potential harm to consumers is identified.”²⁰

Self-regulatory codes must not intend to play a substituting or independent role apart from legislation. However, if properly enforced, they may have an important **role in complementing the legislation**. They may help to ensure that the basic principles are actually achieved in practice, by helping businesses understand how to meet their obligations and reacting speedily to new market practices.²¹

4. Strengths and weaknesses of self-regulation and co-regulation

There are numerous **advantages** of “alternative regulatory methods” such as self-regulation and co-regulation. These include:

- **Removal of barriers to the internal market.** By agreeing common rules at European level (harmonisation) or arranging mutual recognition of national rules, alternative regulatory methods make a significant contribution to the smoother operation of the single market.
- **Reduction of over-regulation at the EU level.** Under the principles of subsidiarity and proportionality, “the Community is obliged to legislate only where it is necessary” . Alternative regulation mechanisms may in some cases provide a good substitute to legal instruments.
- **Easing the workload of regulators.** Co-regulation, in particular, can help to free up legislative channels by allowing the legislator to focus on essential aspects of legislation.
- **Better implementation.** Self- and co-regulatory initiatives can play a facilitating role in applying the principles contained in the legislation.

The important role of self-regulation in complementing EU legislation has been recognised by the 2000 e-commerce Directive²² and the unfair commercial practices proposal²³, which explicitly

²⁰ Speech/03/495, David Byrne, Advertising and Commercial Communication World Federation of Advertisers 50th Anniversary Congress Brussels, 28 October 2003, <http://europa.eu.int/rapid/pressReleasesAction.do?reference=SPEECH/03/495&format=HTML&aged=0&language=EN&guiLanguage=en>

²¹ Ibidem.

²² Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce).

²³ Proposal for a Directive concerning unfair business-to-consumer commercial practices in the Internal Market (the Unfair Commercial Practices Directive), COM (2003) 356, http://europa.eu.int/comm/consumers/cons_int/safe_shop/fair_bus_pract/directive_prop_en.pdf

foresees a role for codes in applying the principles contained in the directive. Likewise, the draft Directive on services in the internal market²⁴ clearly encourages codes of conducts drawn up by interested professions at Community level.

- **More flexibility.** Alternative methods of regulation are speedier and more flexible than traditional legislative channels. For the sectors and professions concerned, they therefore provide an opportunity for adapting more easily to changing environment.
- **Stakeholder involvement.** Self-regulation and co-regulation mechanisms imply wide consultation with all interested parties. This has a potential to create a sense of responsibility among social and economic players.

While offering many advantages, co-regulation and self-regulation raise **a number of concerns**. Most of them have to do with:

- **Safeguarding public interest.** The main concern is that industry might use self-regulation and co-regulation to serve their own commercial interests at the expense of benefit and health of consumers.
- **Enforcement.** Few co-regulation and self-regulation initiatives are subject to monitoring and still fewer to sanctions if their provisions are breached. Even if this is the case, monitoring and sanction mechanisms can prove difficult to implement, overly complex and ineffective (see the example of advertising codes above).

Another potential problem is a proliferation of too many codes and the need for rationalisation (e.g. food codes).

- **Diminution of the role of law.** There is a widespread concern that co-regulation and self-regulation measures might undermine legislation and other forms of binding action by public authorities.
- **Legitimacy.** Co-regulation in particular, can endow private interests with real law-making powers. That weakens the role of the Parliament, the only EU directly elected body.
- **Representativeness.** Not all of the companies involved in a sector may sign up to a self-regulation system which raises questions about effectiveness. The parameters chosen as acceptable by the industry concerned and integrated into a self-regulation system may not coincide with the wider public interest.

Conclusions

The concepts of self-regulation and co-regulation are new in European policy-making and

²⁴ Proposal for a Directive on services in the Internal Market (the Unfair Commercial Practices Directive), COM (2004) 2
http://europa.eu.int/eur-lex/en/com/pdf/2004/com2004_0002en03.pdf

legislation. The legal framework developed by the Inter-Institutional Agreement of December 2003 has yet to be tested and therefore no comments can be made on how it would work in practice.

But a few principles could be made:

There is an important Regulatory role for the EU for the objective of promoting human health. This is a Treaty obligation even if the legislative mechanism to ensure this is lacking.

Self-regulation should not replace the legally binding and well enforced regulation, which is a government role to set minimum rules to protect individuals and society from harm. Self-regulation presents an opportunity for all players in a commercial sector to jointly go beyond existing standards and to improve quality of their products and services as well as to enhance the ethical, social and environmental aspects of their activity. The consensus of the self-regulation system means that no company can gain competitive advantage by undercutting standards and that the benefits of higher standards and quality can be delivered to citizens and society.

Annex 1: European social dialogue procedure (Articles 138-139 TCE)

