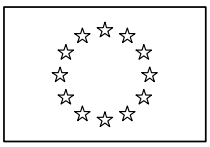

COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING DOCUMENT

Annex to the proposal for a European Parliament and Council Regulation on food additives

IMPACT ASSESSMENT

{COM(2006) 428 final}
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IMPACT ASSESSMENT

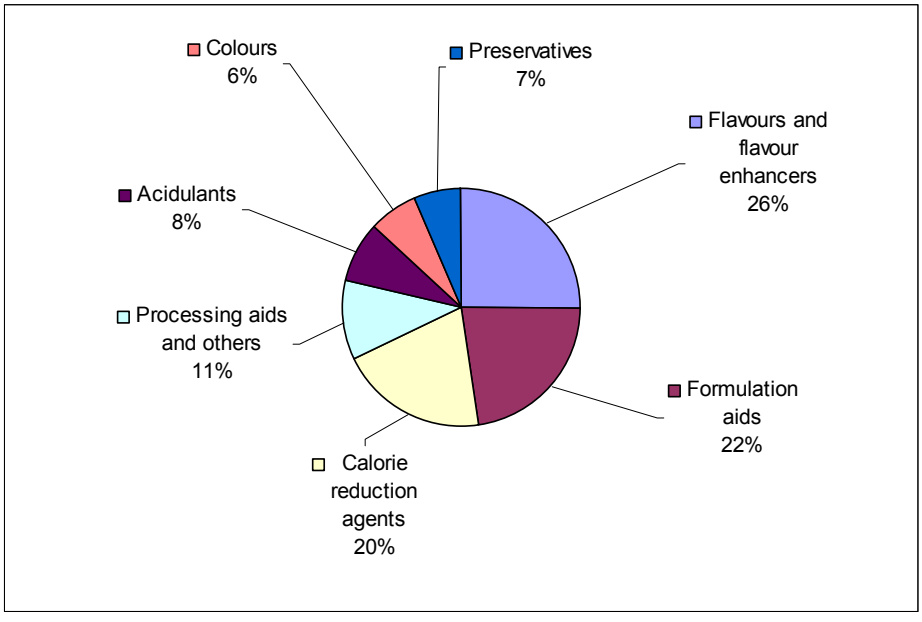
Concerning the proposal for a European Parliament and Council Regulation on food additives

1. INTRODUCTION

Food additives are substances added intentionally to foodstuffs to perform certain technological functions, for example to colour, to sweeten or to preserve. Since ancient times substances have been added to foods to improve the presentation and/or maintain its nutritional quality. For instance saltpetre (containing potassium nitrate) has been used since the middle ages for the preservation of meat products. In modern times food additives are used to facilitate or compliment the wide variety of production methods in the food supply. Their two basic functions are to make food safer by preservation or to make food look or taste better or improve texture.

The additives industry is a dynamic part of the food industry and the total value of the world food additives market was estimated in 2002 at about 20 billion US dollars (including flavourings, vitamins and functional food ingredients). The breakdown of the US market from 2001 was as follows:

Total market US$ 5 billion



Flavourings and flavour enhancers US$ 1.25 billion
Formulation aids US$ 1.1 billion
Calorie reduction agents US$ 1billion
Processing aids and others US$ 535million
Acidulants US$ 410million
Colours (and adjuvants) US$ 320 million
Preservatives US$ 321million

Additional information concerning the food additives market and employment data within Europe was requested from Industry trade associations, however, the data available is limited. The food additives industry is a large employer, however due to its diverse nature it is hard to accurately quantify the scale of employment. The industry ranges from companies which specialise in manufacturing specific additives to sectors of the industry where the food additive production is just one of the uses of the substance. As an example phosphates are used in a wide range of applications and the food additive usage is a small proportion of the total production.

A trade association which represents a number of additive manufacturers was however able to provide the following estimates for the number of employees and factories for the companies within their membership:

	Number of Factories (In EU)	**Approximate number of employees (In EU)**
Colours Sector	40	2000-5000
Emulsifiers Sector	15-30	1000-5000
Biogums Sector	5-10	1000--5000
Glutamate Sector	1	220
Pectin Sector	5-10	na
Cereal Starch industry	37	14000
CEFIC Food additives sector	10-20	1000-5000

Source ELC

Almost all processed foodstuffs contain food additives. As foodstuffs are an important area with respect to cross border trade and consumer safety, there has been a long history of regulation on food additives within the EU. Full harmonisation was achieved through the Framework Directive 89/107/EEC, and subsequent Directives.

Research and development of new technologies and new applications in foods is essential for the food industry to fulfil increasing consumer demands. Therefore, as long as new technologies are deemed safe by the European Food Safety Authority it is important that food additive approvals are both current and easy to update to enable industry to innovate and develop.

These innovations can only be accepted if the human health and the interests of the consumers continue to be assured. A legal framework remains necessary. Such a framework must ensure effective functioning of the internal market and should provide protection of the consumer's health and interest. At the same time it should be assured that the legislation does not hamper creativity and innovation of the European additives industry.

2. PROBLEM IDENTIFICATION

2.1. Existing legislation

Co-decision

Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption[1] establishes the general principles applicable to additives for use in foods:

– It provides definitions for additives and processing aids and sets out the general criteria for the use of food additives.

– It provides rules for the labelling of additives which are intended for sale as such to food manufacturers;

– It provides rules for the labelling of additives which are intended for sale as such to final consumers.

– It provides rules for allowing Member States to provisionally authorise additives within their territories for a maximum period of 2 years to take account of scientific and technical developments whilst awaiting Community approval.

– It requests the adoption of more specific provisions on additive authorisations, methods of analysis and sampling as well as purity criteria.

The provisions on additive authorisations have been enacted by the following legislation which lays down the list of approved food additives and their conditions of use:

- European Parliament and Council Directive 94/35/EC (as amended) on sweeteners for use in foodstuffs

- European Parliament and Council Directive 94/36/EC on colours for use in foodstuffs

- European Parliament and Council Directive 95/2/EC (as amended) on food additives other than colours

[1] OJ L 40, 11.2.1989, p. 27.

Comitology

The Commission has been conferred the implementing power to lay down the specific purity criteria for approved food additives:

- Commission Directive 95/31/EC (as amended) laying down specific criteria of purity concerning sweeteners for use in foodstuffs;
- Commission Directive 95/45/EC (as amended) laying down specific purity criteria concerning colours for use in foodstuffs;
- Commission Directive 96/77/EC (as amended) laying down specific purity criteria on food additives other than colours and sweeteners

2.2. The scope of Directives 89/107/EEC, 94/35/EC, 94/36/EC and 95/2/EC

The provisions relating to food additives need to be amended in several respects. Firstly, implementing powers should be conferred on the Commission to maintain the Community lists of approved additives and the status of enzymes should be clarified. Secondly, the Community lists of colouring matters, sweeteners and other additives need to be simplified.

Article 202 of the EC Treaty provides that in the instruments which it adopts, the Council shall confer on the Commission powers for the implementation of the rules which the Council lays down, save in specific cases where it may reserve the right to exercise directly implementing powers itself. Such transfer of competence should normally allow the Commission to transform rapidly the scientific advice it receives by amending the appropriate legislation or adopting appropriate decisions. In some cases, however, (in particular for food additives) implementing powers have not yet been conferred on the Commission with the undesirable result that updating positive lists of approved substances (whether this is necessary to permit a new substance, to ban the use of an approved substance, or to modify the conditions of use of a substance) can take several years after the formulation of the scientific advice.

As stated above the list of permitted food additives and their general conditions of use are contained within four Directives. Revision of authorisations is only possible via co-decision procedure which can often take several years from the scientific evaluation to the implementation of a directive into national law. The implications of this lengthy procedure are that innovation and development of new additives is stifled due to delays and uncertainty of the outcome in approving new additives. More importantly this also leads to delays in amending the current community positive list of additives as a result of new scientific data.

Article 1 of Directive 89/107/EC defines processing aids and stipulates that the Directive does not apply to substances when used as processing aids. The definition of processing aids is "any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect in the finished product". However, this definition, although clear in intention, is often interpreted in different ways by Member States and the food industry and gives rise to in-depth and complicated discussions on substances which fall on the borderline between additive and processing aids. It may therefore be appropriate to propose a clarification of the definition with the intention of removing some of the current uncertainties and discussion regarding borderline cases.

At community level only the use of carriers in additives is harmonised. The 5th amendment to the Directive 95/2/EC adopted in December 2003 widened the scope to regulate the use of all additives used in flavourings. In order to further clarify the legislation and improve cross border trade, the scope of the Legislation should be extended to harmonise also additives other than carriers used in additives (e.g. a preservative used in a food colouring). Because food enzymes are being proposed for harmonisation the use of additives in these substances should also be harmonised. More importantly this extension of the scope allows such uses to be considered when determining the overall intake of additives.

The framework legislation was developed before legislation on genetically modified food and feed (Regulation 178/2002) was introduced. This Regulation includes food additives in its scope as regards the evaluation for safety of additives produced from a genetically modified source or of additives containing or consisting of genetically modified organisms. There is no reference in the current additive legislation that the GM food feed Regulation is part of the authorisation process for genetically modified food additives.

2.3. Scientific and technological developments

The food additive industry is continually striving to develop improved technology and processes to innovate and improve food manufacture. They are however restricted under the current additive approval procedures as it can often take several years after a new additive or use has been evaluated for safety by EFSA before it can be used across the EU. These delays are a result of the time required for the co-decision procedure and also time required in implementing the legislation in all Member States. An improved process is required which would allow European industry to benefit from such innovations and developments in a timely fashion and enable benefits from innovation to be felt sooner. However, an accelerated process must not reduce the time required for new additives or uses to undergo an appropriate safety evaluation.

2.4. Information to the consumer

Consumers are being informed on the presence of food additives through labelling. Labelling rules exist for:

– additives sold as such to food manufacturers,

– additives sold as such to final consumers and

– additives present in foods intended for final consumers.

Labelling of additives sold as such to food manufacturers and to final consumers is covered by Directive 89/107/EEC. The rules on labelling on additives in foods are controlled by Directive 2000/13/EC. These rules should remain consistent. However, at the moment, the labelling rules for additives sold to the manufacturer or to the final consumer are not in line with requirements for labelling of foodstuffs that contain genetically modified food additives.

3. POLICY OBJECTIVES

The policy objectives to be met are:

– the protection of human health and consumers' interests;

– to simplify food additive legislation for principles, procedures and approvals;

To this end specific objectives will be:

– to confer the implementing powers on the Commission to update the Community list of authorised food additives;

– to consult the European Food Safety Authority (EFSA) for the safety evaluation of food additives;

– to set up a re-evaluation programme for existing food additives;

– to require the authorisation of additives that consist of, contain or are produced from genetically modified organism under Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

As a consequence these objectives will contribute to the strategic objectives of the Commission as set out in the Lisbon Strategy, the Commission five year plan and the Commissions White paper of Food Safety published in 2000.

4. CONSULTATION WITH THE COMPETENT AUTHORITIES OF MEMBER STATES AND STAKEHOLDERS

It should be noted that on the basis of the comments received during the last consultation, certain provisions of the Commission proposal were reformulated. The main changes are described in Section 7. The impacts of the reformulated Commission proposal are assessed in Section [6]

The opinions of Member States competent authorities and stakeholders have been assessed through targeted consultations in the different working groups (see section 8) and during bilateral contacts where working documents have been discussed. In addition on 22 February 2005 a working document for a proposal on food additives and a relevant questionnaire was circulated to the Member States and the different stakeholders. With a view to prepare this impact assessment, the questionnaire aimed to solicit responses on the following issues:.

4.1. Clarification of the Scope of the Regulation

4.1.1. Simplification of the legislation

It was proposed to bring together all additive legislation (sweeteners, colours and others) into one single instrument and also introduce faster procedures to enable the legislation to be updated (comitology). This would ensure that the legislation will be simpler to understand and follow.

Member States	++
Manufacturer of additives	++
Importer of additives	++
User of additives	++
Consumer Organisations	+
Trade association	++

The approach to bring all food additives legislation into one instrument was generally welcomed by stakeholders. Consumer organisations, however, have voiced some concern that the introduction of comitology may reduce the overall transparency of the process, where additions to the positive list will no longer be scrutinised and debated to the same extent by the European Parliament.

4.1.2. Revised definition of processing aids.

Clarifying the definition of processing aid will reduce confusion over the status of such substances used in food manufacturing in the EU. This will improve the functioning of the market and will also ensure that consumers are fully knowledgeable and assured that the safety of substances which have been intentionally added and remain in their foodstuffs have been assessed for safety. It was proposed that the definition of processing aid be amended to only include substances for which a removal step has been attempted.

Member States	++
Manufacturer of additives	--
Importer of additives	--
User of additives	--
Consumer Organisations	++
Trade association	--

Consultation with stakeholders revealed that there are strong opinions on this subject. Generally Member States and consumer organisations support the principle of the new definition as it will lead to greater level of information to consumers, although some concerns have been expressed relating to labelling implications. Responses from the food industry have however been negative to this change. Although it was recognised that the current definition can cause interpretative problems it was felt that the proposed approach could introduce further problems, including; unclear labelling for consumers where substances would appear on a label although they are no longer present in the foodstuffs in the same form and also labelling discrimination where a substance could require labelling if added directly to the food but not if added via a intermediate product and not having a function in the final food (carry over provision).

In addition, if this revised definition is adopted, industry would require a suitable transition period to allow those additives which are currently considered as processing aids to be evaluated and approved where necessary or to allow alternatives to be developed.

It was also mentioned that changing this definition may create a divergence from international definitions such as CODEX.

4.1.3. Inclusion of additives in additives

It is proposed that the scope of the Regulation should be extended to also harmonise the use of additives in additives and enzymes (e.g. a preservative used in a colouring preparation), this would be in line with the situation of additives in flavourings covered by the current legislation. This aspect should have a limited impact as it will reflect current industry practice, however there may be some instances where substances used in additive preparations are not currently approved additives, and therefore users will either have to reformulate or apply for the approval of the substance as new additives.

Member States	++
Manufacturer of additives	+
Importer of additives	+
User of additives	+
Consumer Organisations	++
Trade association	+

There is general agreement that this is a positive move but industry have expressed a concern that a suitable transition period should be permitted to both allow the necessary data to be prepared for any new additives requiring evaluation and also to allow current stocks to be used up.

4.2. 10 Year Authorisation for additive approvals

4.2.1. Impact of time limited authorisation.

The proposal reflects that the regulation and authorisation of additives should remain current and therefore the positive list should only contain additives which are still used. A 10 year authorisation procedure was included to enable interested parties to indicate whether additives are still required for particular applications.

Member States	+
Manufacturer of additives	-
Importer of additives	-
User of additives	-
Consumer Organisations	+
Trade association	-

There was a strong indication from industry that a time limited authorisation could be a barrier to innovation and would introduce uncertainty and a lack of stability in the additives market. On the other hand Member States and consumer organisations considered that additive approvals should be kept under some form of review to ensure that the Regulation remains current. It was never the intention that the 10 year authorisation would be an onerous task but instead would be an effective administrative measure to ensure that additive authorisations are still necessary from a technical standpoint. This measure is independent from the safety evaluation as it will still be possible to request a re-evaluation of an additive at any stage in the light of any safety concerns which come to light.

4.2.2. Status of time limited authorisation

	Fixed period of time	**Fixed period of time expanded tacitly if no negative information received**	**No fixed time period**
Member States	6	8	
Manufacturer of additives		2	11
NGO	2	1	
User of additives	2	7	6
other	1	1	1
Trade association		4	13

As described above there were strong views on the status and duration of a time limited authorisation and the majority of respondents were more open to either no fixed time period or a fixed period of time which would be expanded unless negative information was received.

4.3. Introduction of comitology

4.3.1. The effect of innovation and R&D as a result of the use of comitology procedures

Member States	+/-
Manufacturer of additives	+
Importer of additives	+
User of additives	+
Consumer Organisations	+/-
Trade association	+

Member States and stakeholders are generally positive to the use of comitology procedures for updating additives legislation as the timescales needed to obtain and benefit from new additive authorisations will be greatly reduced, however consumer organisations have some reservations over the transparency of such procedures.

4.3.2. Effect of removing the two-year temporary National Authorisation procedure.

With the introduction of comitology the necessity for maintaining the two year temporary national authorisation procedure is reduced. The food industry has however expressed some reservations that the current temporary authorisation system should remain in place for a transition period until the comitology procedures are operational.

5. POLICY OPTIONS

5.1. No action

No action would mean the current regulatory situation would be maintained. The process of amending additive authorisations would still require the lengthy co-decision procedure. As regards the safety evaluation of new food additives, EFSA will not be required to complete the evaluation within a fixed time period nor will it be required to carry out a review reassessing all currently authorised additives. The use of food additives in additives and enzymes will not be harmonised, therefore, the Member States legislation remains in place. The labelling rules for additives sold to the manufacture or to the final consumer will not be brought in line with labelling Directive 2000/13/EC

5.2. Non legislative action

A code of practice for the safe use of food additives in additives and enzymes could be elaborated by industry in combination with self-controlling actions. The use of food additives in additives and enzymes could be allowed without requiring prior authorisation. For these uses of additives to be recognised as safe, industry would have to ensure compliance with the code of practice. Under the principle of mutual recognition free movement of products within the Single Market would be ensured subject to the exceptions provided for by the Treaty.

5.3. Legislative action

In the legislative option there are two possibilities: to amend the existing framework directive 89/107/EEC or to propose a new regulation replacing the existing co-decision directives (framework directive and the three specific directives on colours, sweeteners and other additives).

Amending Council Directive 89/107/EEC

By amending the framework directive, the Commission can request for implementing powers for authorisations of food additives. The scope of the directive can be clarified. The labelling rules contained in the Directive can be brought into line with Directive 2000/13/EC. Harmonisation of the use of additives in additives and enzymes can be regulated although a separate implementation measure would be necessary in addition. Procedures for safety evaluation by EFSA can be laid down and the re-evaluation of all currently authorised food additives can be required.

Proposal for a new Regulation

By proposing a new regulation replacing the existing co-decision directives (framework and the specific directives on colours, sweeteners and other food additives), the current legislation can be significantly simplified. The Commission can request for implementing powers for authorisations of food additives. All the principles that govern the use of food additives can be found under one instrument. Likewise all the authorisations of the use of food additives in foods can be found under a single instrument. Both the scope and the definitions on functional classes of food additives (including carriers) can be clarified. The labelling rules on food additives sold to the manufacturer or to the final consumer can be brought into line with Directive 2000/13/EC. Harmonisation of the use of additives in additives and enzymes can be achieved through a single instrument. Procedures for applications for authorisations and for safety evaluation by EFSA can be laid down and the re-evaluation of all currently authorised food additives can be required.

5.4. Deregulation of additive legislation

All the specific food additive legislation could be revoked as the Regulation (EC) No178/2002 laying down the general principles and requirements of food law is now in place in the European Community. This Regulation requires that food shall not be placed on the market if it is unsafe. It also provides for safeguard measures in case a Community wide emergency measure is necessary.

Food additives and foods containing food additives would thus continue to circulate in the internal market based on the principle of mutual recognition. A Member State may not forbid the sale on its territory of a product lawfully produced and marketed in another Member State, even if that product is produced according to different technical or quality specifications from those applied to its own products. The Member State of destination may waive this rule only under very strictly defined circumstances, where overriding requirements of public interest, such as health, are at stake. Moreover, in the absence of harmonisation, in a sense of 'mutual recognition' of risk assessment, Member States should take account of technical or chemical analyses or laboratory tests which have already been carried out in another Member State (*Brandsma*, paragraph 12).

6. IMPACTS

6.1. No action – impacts

Economic impact

- The process of amending additive authorisations would still require the lengthy co-decision procedure including the time spent by the Member States on implementing the authorisation. This will continue to act as a barrier to innovation by industry, whereby new technological developments would not be encouraged.

Social impact

- EFSA will not be required to carry out a review reassessing all currently authorised additives.

- Consumers would not benefit from the additional controls on the use of additives used in food additives and enzymes

Environmental impact

- There would be no environmental impacts from any of the policy options considered, since the industry concerned – the food industry – is involved in secondary or tertiary processing of food products. Additives are already widely available and widely used.

6.2. Non legislative action

Economic impact

- The process of amending additive authorisations would still require the lengthy co-decision procedure including the time spent by the Member States on implementing the authorisation. This will continue to act as a barrier to innovation by industry, whereby new technological developments would not be encouraged.

- Member States and stakeholders would have to elaborate and agree a code of practice on the use of additives in additives.

Social impact

- Consumers would not benefit from increased assurance on the safety of food. Substances which are added to foods during processing and are present in foods as consumed would not be subject to harmonised risk assessment if they are not exerting a technological affect.

Environmental impact

There would be no environmental impacts from any of the policy options considered, since the industry concerned – the food industry – is involved in secondary or tertiary processing of food products. Additives are already widely available and widely used.

6.3. Legislative option

This action will affect all food additive manufacturers and will have some consequential impacts on the food industry.

Economic impact

6.3.1. Impact on competitiveness, markets, trade and investment flows

Additive legislation is already harmonised across the European Community, many aspects of the proposed legislative action will therefore have a limited impact. Of significance will be the introduction of comitology to the authorisation of additives. The overall time spent on procedures and implementations can be shortened by comitology procedure and by setting up a regulation thus not requiring implementation by the Member States. This has the potential to stimulate investment in developing new additives as it removes many of the delays currently associated with realising the benefits of such developments.

6.3.2. Impact on direct and indirect costs imposed on businesses

This proposal will have a limited effect on direct and indirect costs for businesses. There will be some costs associated with changes to the regulation of additives in additives and enzymes and also associated to this in maintaining product data sheets. However, these will be one off costs and a suitable transition period will be included to allow time to adapt to these changes. These costs will be associated with the requirement to evaluate substances not contained within the list of authorised additives which are currently used in additives and enzymes. It is however anticipated that the number of substances affected will be low and the costs associated will be in line with those for other new additives.

6.3.3. Impact on the administrative requirements imposed on businesses

There will be a limited impact of administrative requirements imposed on businesses as a result of this proposal. Any such impact will be similar to those described above in preparing applications requesting authorisation for new substances which are used in additive preparations but not already approved as additives.

There will also be a positive impact on administration for the food industry as this proposal will lay down a greater degree of structure to the procedures for authorising new additives or for amending current additive authorisations. As a consequence companies with applications for new additives will benefit from greater certainty over the approval process and a better understanding of the timetable.

6.3.4. Impact on innovation and research

- The proposed action will have a positive impact on innovation. By using comitology the time period between a positive evaluation of a new additive by the EFSA and its authorisation across the EU will be drastically reduced, thus allowing manufacturers to market and sell such additives in a shorter timescale and therefore able to recoup development costs.

- The requirement for additive manufacturers and the food industry to notify the Commission when additives are no longer required for particular uses, will have a positive impact whereby redundant uses of permitted additives can be removed thus making the additive available for new uses where appropriate.

6.3.5. Impact on consumers

This proposal will have a very limited economic impact on households. Any costs associated with additional evaluations are unlikely to increase the cost of goods sold to consumers.

6.3.6. Impact on specific regions, sectors or workers

This proposal will not have specific impacts on any particular regions, sectors or workers.

6.3.7. Impact on third countries and international relations

This proposal will further harmonise the legislation on additives and will create a uniform market within the EU.

6.3.8. Impact on public authorities

Public authorities in Member States are already tasked with implementing and enforcing harmonised legislation on food additives and this proposal will not significantly increase this work.

Social impact

6.3.9. Impact on consumer rights

- Consumers will benefit from increased assurances on the composition and safety of the food which they purchase.

- Consumer organisations, however, have voiced some concern that the introduction of comitology may reduce the overall transparency of the process, where additive approvals will no longer be scrutinised and debated to the same extent by the European Parliament. The use of comitology is however appropriate as food additive legislation is one of the few areas in food law where co-decision is still required for largely technical amendments. Consumer need and technological benefit will remain as important parameters to be considered by Member States representatives when additives uses are debated under the comitology procedure. In addition to formal comitology procedures other methods of consultation will continue. These will include routinely publishing agendas for standing committee meetings on the website and amendments to legislation will also be considered in expert working groups or other fora to which consumer groups and other stakeholders are routinely invited.

6.3.10. Impact on public health and safety

Harmonised legislation which takes into account the safety of additives permitted in foodstuffs is already in place in Member States. This action is unlikely to have a significant impact on public health and safety although it will require further substances which are added to foodstuffs to be evaluated for their safety before they can be added to the list of permitted additives.

Environmental impact

There would be no environmental impacts from any of the policy options considered, since the industry concerned – the food industry – is involved in secondary or tertiary processing of food products. Additives are already widely available and widely used.

6.4. Deregulation of additive legislation

Economic impact

Deregulation could result in different risk assessments being undertaken for additive between Member States. Member States could also stipulate different procedures for approval. Such a move would therefore have an impact on the administrative burden for the competent authorities of Member States in undertaking this additional work.

Deregulation would also present a considerable additional administrative burden on food additive manufacturers whereby it would be necessary to apply for authorisation individually in all the Member States in which they wish to use the additive. This would also have an effect on the food industry and international trade.

Although the principle of 'mutual recognition' would apply some distortion of the market would be expected. This would be due to potentially different interpretations of risk assessments. Cross border trade would therefore be impacted and some manufacturers would gain a competitive advantage depending upon the country in which they are based.

Social impact

Although the general principles of food law apply, the deregulation of additives legislation could still lead to a deterioration of consumer protection relating to food additives. This could arise due to different degrees of risk assessment being carried out in Member States combined with potential differences in interpretation of such assessments. The resulting divergence in additive authorisations would also complicate procedures for estimating and comparing the intake of permitted food additives across the European Union and within individual Member States where imported foods would be subject to different additive authorisations.

Environmental impact

There would be no environmental impacts from any of the policy options considered, since the industry concerned – the food industry – is involved in secondary or tertiary processing of food products. Additives are already widely available and widely used.

7. CONCLUSION

On the basis of this impact assessment, the conclusion is that the policy objectives are best achieved by legislative action.

A substantial amendment to Council Directive 89/107/EEC is necessary to take into account the issues described above. However, to fulfil all the policy objectives, it is not sufficient to amend the framework directive but it is necessary to bring together all additive legislation into a single instrument. Therefore, it is proposed that Directive 89/107/EEC and the specific food additive directives are replaced by a new Regulation on food additives and a separate Regulation which sets up common procedures for food additives, food enzymes and food flavourings with the following objectives:

7.1. Simplification

This will simplify the current regulatory framework on food additives by creating principles, procedures and authorisations of food additives. By introducing the comitology procedure for authorisation of food additives, the overall administrative time spent on the authorisation can be reduced significantly. The purpose of this legislation is to improve harmonisation of additives legislation between Member States by making approvals directly applicable (regulation), therefore, with the introduction of comitology procedures it is not appropriate to maintain the temporary national authorisation procedure.

7.2. Clarification of the scope

The Regulation widens the scope of additive legislation to include additives used in additives and enzymes. As a response to the concerns raised by the industry, a transition period is introduced in order to allow the necessary data to be prepared for any new additives requiring evaluation and also to allow current stocks to be used up. This Regulation will also remove from its scope enzymes used for additive functions as these will be regulated by a separate proposal for a Regulation on food enzymes.

During the development of this proposal it was considered to revise the definition of processing aid to create a clearer distinction between such uses and those of additives. Such a move could reduce interpretation difficulties and possibly improve trade both within the EU and with imports and exports whereby a clearer definition would create greater legal certainty. Additionally although it was considered by some that such a move would create a divergence from other international definitions such as that used in Codex it could have provided a starting point for the update of the codex definition which is also already subject to different interpretations.

This aspect of the draft proposal created a great deal of concern for the food industry. They stated that a number of substances which are not intentionally removed would henceforth be classed as additives and require labelling and that such a change would introduce additional confusion in labelling and also considerable burden to the industry. This latter point was made stating that in many cases such substances would either be no longer present in the form in which they were added or they would no longer be exerting an effect on the foodstuff. It was then considered that new definition proposed could have been developed so that substances which are affected by the definition change but no longer exerting a technological affect in the final food would require a harmonised safety evaluation and authorisation via a positive list, but could exempted from labelling. Although such a move would alleviate the industry's concerns over labelling the burden of evaluation was deemed to be too high.

Taking into account these views and the concerns of industry that such a change would have a significant impact, it has been decided that at this stage the processing aid definition should remain unchanged. Therefore the current interpretation difficulties will continue and will have to be solved on a case by case basis, until either a revised definition can be agreed or guidance on interpretation can be developed.

7.3. Better protection of the health of the consumer

One of the guiding principles of the use of additives is that they must not present a hazard to the health of the consumer at the level of use proposed. Therefore before additives are permitted they must first be evaluated for safety by the European Food Safety Authority (previously undertaken by the Scientific Committee on Food). This proposal will continue this procedure but will strengthen the requirement that EFSA undertake the safety evaluations for new additives in order to separate risk management from risk assessment decisions. This proposal also sets out a requirement for EFSA to carry out a programme of safety assessment on all currently permitted food additives, in addition to assessing new additives as they are submitted for evaluation.

Additionally the proposal introduces a requirement to ensure that all additives which consist, contain or are produced from genetically modified organisms should be authorised in respect of the genetic modification according to Regulation (EC) No 1829/2003 on genetically modified food and feed prior to being permitted under additives legislation.

To this end, the Regulations will lay down

– Community procedures for the evaluation and approval of food additives.

– A requirement that for all permitted food additives a specification must be laid down containing the criteria on purity and defines the origin of the food additive.

– A requirement that additives used in additive or enzyme preparations will be controlled and evaluated in a similar manner to additives used in flavourings and flavouring preparations.

It should be foreseen that the regulation can easily be adapted to new scientific evidence so that the health of the consumer can be protected in an efficient way.

During the development of this proposal it was considered whether a time limit for additive authorisations should be introduced, however the food industry considered this to be an administrative burden and could destabilise the additives market. In the event of a safety concern, the Commission can anyway act at any time, time limited authorisations are not included in this proposal. It is however important to include a measure to ensure that the list of permitted additives and their conditions of use remain current and promote innovation and competitiveness. Therefore, an obligation will be introduced whereby food additive manufacturers or users are obliged to inform the Commission and Member States when currently permitted additive uses are no longer necessary as a result of technological progression. Such notifications will enable the Commission, if appropriate, to propose amendments to the current list of permitted additives.

7.4. Better Information to the consumer

Better information and more clear information must be provided to the consumer. To this end:

– The labelling requirements of food additives sold to the manufacturer or directly to the consumer will be updated in particular to inform where the additive consists, contains or is produced from genetically modified organisms. The wording of such is in line with the Regulation (EC) No 1829/2003 on genetically modified food and feed.

8. OVERVIEW CONSULTATION

CONSULTATION WITH THE STAKEHOLDERS ON FOOD ADDITIVES AND ENZYMES

Some of the Stakeholder organisations involved:

BEUC (The European Consumers' Organisation)

CIAA (Confederation of the food and drink industries of the EU)

ISA (International Sweeteners Association)

CEFIC (European Chemical Industry Council)

AMFEP (Association of Manufacturers and Formulations of Enzyme products)

ELC (Federation of European Food Additives and Food Enzymes Industries)

FEDIMA (Federation of the Intermediate products Industries for the Bakery and Confectionery trades in the EEA)

CAOBISCO (Association of the Chocolate, Biscuit and Confectionery Industries of the EU)

Meetings at which the abovementioned stakeholders and governmental experts from Member States were consulted on a revision of the Framework legislation on **food additives**:

– 11-12 October 1999

– 24-25 January 2000

– 3-4 July 2000

– 6 June 2001

– 11 September 2003

– 3 June 2004

– 22 February 2005

Other consultations:

– EFSA consultation 13 May 2004