COUNCIL OF THE EUROPEAN UNION

Brussels, 4 September 2006

12179/06 ADD 1

Interinstitutional File: 2006/0144 (COD)

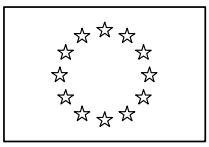
DENLEG 40 CODEC 827

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	31 July 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	Commission staff working document Annex to the proposal for a regulation of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, and Council Directive 2001/112/EC Impact assessment

Delegations will find attached Commission document SEC(2006) 1045.

Encl.: SEC(2006) 1045



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28.7.2006
SEC (2006) 1045

COMMISSION STAFF WORKING DOCUMENT

Annex to the proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, and Council Directive 2001/112/EC

IMPACT ASSESSMENT

{COM(2006) 425 final}
{SEC(2006) 1044}

TABLE OF CONTENTS

IMPACT ASSESSMENT

Concerning the proposal for a European Parliament en Council Regulation on food enzymes

1. INTRODUCTION

Over the last 25 years, the use of enzymes and enzyme preparations has steadily increased in all sectors of the food industry. Enzymes are generally used as processing aids since most are used during food processing and usually only remain in the food as consumed in an inactivated form.

Traditionally enzymes have played an important role in food manufacture in the production of foods such as bread, cheese, beer and wine. For example in bread-making the enzyme, amylase breaks down flour into soluble sugars, which are subsequently transformed by yeast into alcohol and carbon dioxide which makes the bread rise.

Enzymes are used for an increasing range of applications: bakery, cheese making, starch processing and production of fruit juices and other drinks. Here, they can improve texture, appearance and nutritional value, and may generate desirable flavours and aromas.

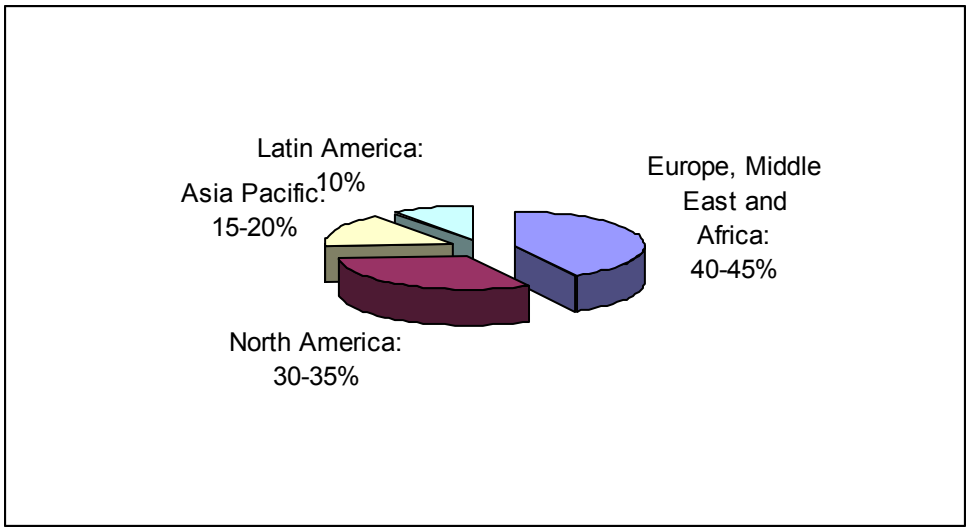
In food production, enzymes have a number of advantages:

- They can be used as alternatives to traditional chemical-based technology, and can replace synthetic chemicals in many processes. Such uses can improve the environmental performance of production processes, through lower energy consumption and biodegradability.

- They are more specific in their action than synthetic chemicals. Therefore, processes which utilise enzymes have fewer side reactions and waste by-products, resulting in higher quality purified products.

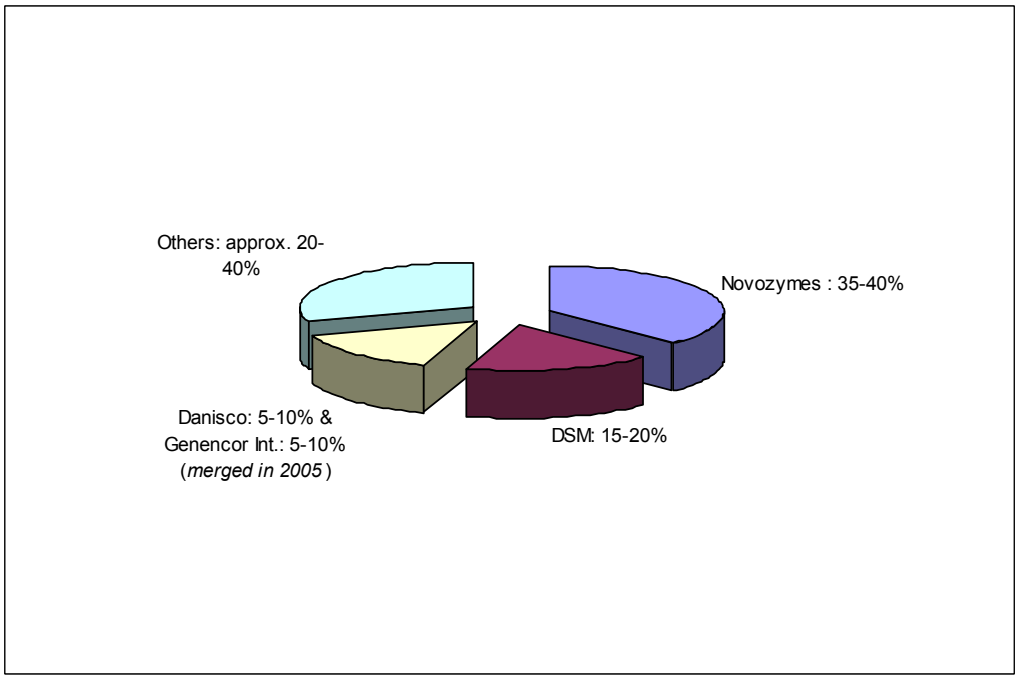
- They allow some processes to be carried out which would otherwise be impossible. An example is the production of clear apple juice concentrate, which relies on the use of the enzyme, pectinase.

Figure 1: Overview of the estimated world wide sales and use of food enzymes (source *Amfep*).



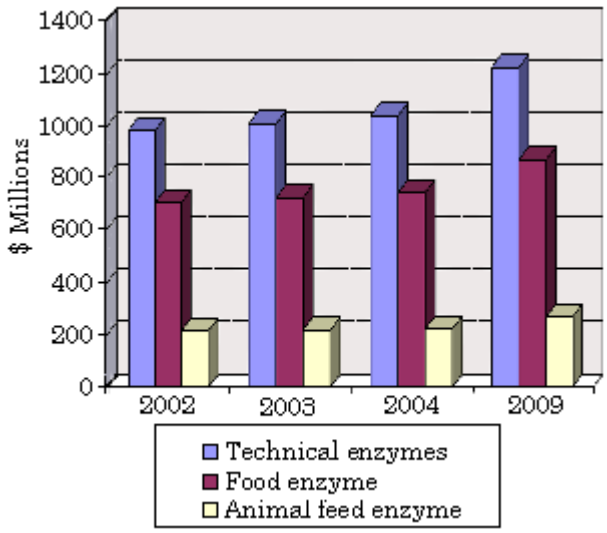
The world wide market of food enzymes is dominated by a number of multinational companies; approximately 60-80 % of the market belongs to 4 companies.

Figure 2: World wide market share for food enzymes companies (*source: Amfep*)



The world market value of food enzymes is estimated to be 650-750 million Euros.

Figure 3: Global Enzyme Markets Based on Application Sectors, 2002-2009 ($ Millions)



Source: *Business Communications Company, Inc. (BCC, Inc.); Market Research Report "Enzymes for Industrial Applications", published in December 2004*

Employment statistics related to food enzyme manufacture within Europe were requested from industry trade associations, but data was not available because a significant part of food enzymes production is done by companies which also produce technical enzymes for uses other than food processing.

Specific economic statistics concerning the use of food enzymes in different food segments could not be provided by the industry trade associations. However, bakery enzymes, starch and sugar processing enzymes and dairy enzymes are reported to be the three largest segments of the food enzyme industry.

The food enzyme industry is a very dynamic part of the food industry. New high specialised enzymes are developed and produced for specific uses with a subsequent improvement in food production and reduction of waste. A *Frost & Sullivan* study (*European Markets for Enzymes in Food Applications, published 29 Apr 2005*) suggests that developing innovative products is crucial for long term survival in the European Food Enzymes Market. Research in this field places emphasis on improving the quality of the products currently available, and on developing novel enzymes for specific niche applications. Increased investments are being made throughout the industry in research and development, especially on patents and licenses for new products.

Since the early 1980s, companies which produce food enzymes have been using genetic engineering techniques to improve production efficiency and quality and to develop new products. However, progress in this field is being slowed down because of the fervent debate on genetically modified foods. According to information provided by AMFEP[1] at least 30% of the food enzymes marketed in Europe today are produced with the aid of genetically modified micro- organisms (GMMs). This figure does not say anything about the actual volumes being produced or the number of foods in which these enzymes are used.

Innovation is thus important for the food enzymes sector however, it can only be accepted if the human health and the interests of the consumers continue to be assured. Currently food enzymes are subject to differing regulatory approaches across the European Community with resulting trade barrier difficulties.

2. PROBLEM IDENTIFICATION

2.1. Existing legislation and lack of harmonisation

The legislation controlling the use of enzymes in food processing is not fully harmonised in the EU. Currently, enzymes used in food processing are considered to be either food additives or processing aids. The definitions of food additives and food processing aids are given in Council Directive 89/107/EEC. Food additives are essentially substances that are added to food and have a technological function in that food, while processing aids are essentially substances that are added during food processing for technical reasons and which may result in the unintentional but technically unavoidable presence of residues of the substance in the final food, but do not have a technological function in the final food.

Council Directive 89/107/EEC covers only enzymes used as food additives and only two enzymes (lysozyme and invertase) are authorised under this Directive. The remaining enzymes are not regulated at all or are regulated as processing aids under the legislation of some Member States.

The national regulatory context of enzymes used as processing aids in food production differs significantly among Member States. Only a few Member States have a mandatory or voluntary authorisation procedure, the majority have none at all. Moreover, there are divided opinions among Member States in relation to the categorisation of enzymes into food additives or processing aids according to their function in the food process or in the final food. The processing aid definition in Directive 89/107/EEC, although clear in intention, is often interpreted in different ways and gives rise to in depth and complicated discussions on substances which fall on the borderline between additive and processing aids.

---

[1] AMFEP represents approximately 90% of the total EU enzyme industry. The following companies/associationsare members of AMFEP: AB Enzymes, Ajinomoto, Amano, AMAFE (Association of Manufacturers of animal based food enzymes), Begerow, Beldem, Biocatalysts, Biochem Europe, Biovet, Chr. Hansen, Danisco, DSM, Erbslöh, Genencor International, Henkel, Kerry BioScience, Lyven, Novozymes, Stern-Enzyme.

Currently, there is no safety evaluation of food enzymes at European level and no authorisation procedure, except for those that are considered as food additives. In addition the lack of harmonised rules in the Community creates barriers to trade for the food enzyme manufacturing business. Since 1997 the food enzymes producing industry has pointed out that the absence of harmonised EU legislation has created unfair commercial practices, hindered growth in this field and led to what is known as 'reverse discrimination' against domestic food producers in countries with more restrictive rules. Industry has since urged for harmonised legislation with a Community procedure for authorisation of food enzymes instead of multiple national authorisations.

As part of the framework to improve Community legislation in the area of foods, the European Commission stated in the White Paper on Food Safety, that the (legal) status of enzymes should be clarified and that specific provisions will be laid down in respect to enzymes.

2.2. Scientific and Technological developments

The food enzyme industry is continually striving to develop improved technology and processes to innovate and improve food manufacture. Historically, enzymes used in food processing are considered to be non-toxic. However, there are some potential hazards arising from their chemical nature and source such as allergenicity, activity-related toxicity, residual microbiological activity, and chemical toxicity. These aspects should be addressed, especially as the development of food enzymes has become through the years more complex and sophisticated. Therefore safety evaluation of all food enzymes, including those produced by genetically modified micro-organisms, is essential in order to ensure consumer safety.

2.3. Information to the consumer

Concerning the labelling of food enzymes, it should be distinguished if they are sold as such or used in food:

– Food enzymes sold as such to food manufacturers,

– Food enzymes sold as such to final consumers and

– Food enzymes present in foods intended for final consumers.

Labelling of food enzymes sold as such to food manufacturers and to final consumers is currently covered by Directive 89/107/EEC only for the two enzymes which are authorised as food additives. All the remaining enzymes, which are considered as processing aids, are excluded from Directive 89/107/EEC.

The question whether the use of food enzymes has to be indicated on the final food depends again on whether the enzyme has been used as an additive or as a processing aid. According to Directive 2000/13/EC on food labelling, processing aids do not have to be mentioned on the label of the final food. The majority of food enzymes are currently considered as food processing aids and hence are not labelled. The consumer needs to be informed about the presence of food enzymes in his food in a balanced, clear and consistent way.

3. POLICY OBJECTIVES

The policy objectives to be met are:

– the protection of human health and consumers' interest;

– the promotion of fair trading in food enzymes in order to ensure an efficient and internationally competitive food industry ;

To this end the specific objectives will be:

– to ensure that the safety of all food enzymes, including those used as processing aids and those produced using genetically modified organisms ('GMO'), is assessed;

– to prevent misleading conduct;

– to provide, where necessary, adequate information relating to food enzymes to enable consumers to make informed choices.

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 and the impacts of the reformulated Commission proposal are assessed in Section 6.3.

In 2000, a task force under the Scientific Cooperation (SCOOP) system, performed a study on enzymes used in foodstuffs and collected data from across the EU. The report[2] concluded that "A consensus was obtained to assert that, in all cases, whatever the status or the categorisation of the enzyme, a rational for safety evaluation is necessary".

The need and impacts of different policy options and especially of a legislative proposal have been assessed through consultations with Member States and stakeholders at the different working groups (see section 8) and during bilateral contacts where working documents were discussed.

On 22 February 2005 a working document for a proposal on food enzymes 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 get responses mainly on the following issues:

4.1. Harmonisation and scope of legislation

The Commission proposal will harmonise legislation on food enzymes throughout the European Union, the introduction of such legislation therefore has the potential to make a large impact. Stakeholders were asked to indicate whether this harmonisation would have a favourable, unfavourable or neutral impact.

The responses to this question were varied and some specific aspects of the proposal were thought to be unfavourable by the food industry in particular. However, the introduction of specific harmonising legislation on enzymes was generally welcomed by all stakeholders. Aspects which it was felt could have an unfavourable impact related to labelling, time limited authorisations and delays in marketing and utilisation of new enzymes under the proposed Regulation. These matters will be discussed further below.

[2] The report was published on: http://europa.eu.int/comm/food/fs/scoop/7.4.1_en.pdf

4.2. Harmonisation of safety evaluation

Responses to the questionnaire indicated that between 100 and 250 enzymes were likely to fall within the scope of the Regulation. As authorisation of enzymes is already required in some Member States, industry was generally positive to the introduction of a European wide safety evaluation as this would bring about a positive effect on single market trade. Industry estimates that trade to third countries may be affected as enzymes would first need to be permitted within the EU before they can be traded to third countries.

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

4.3. Revised definition of processing aids

The definition of processing aid is contained with additives legislation, however if this was to be amended this could have an impact on the enzyme industry. Clarifying the definition of processing aid would reduce confusion over the status of such substances used in food manufacturing in the EU, which are currently subject to differing considerations. This would improve the functioning of the market and would also ensure that consumers are fully knowledgeable to the composition of their foodstuffs. Consultation with stakeholders has revealed that there are strong opinions on this subject.

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

Generally Member States and Consumer organisations support the principle of the new definition as it would reduce confusion as to whether a substance should be considered as a food additive or as a processing aid. In general, Member States also felt that this change would lead to greater level of information to consumers, although some concerns have been expressed with regard to labelling implications.

Responses from the food industry have however been negative to this change, although it is widely recognised that the current definition can cause interpretative problems. They feel that the proposed approach would introduce further complications, including unclear labelling for consumers where substances would appear on a label even if they are no longer present in the foodstuffs in the same form.

With particular emphasis on enzymes, generally the food industry felt this would have a significant impact. It was considered that rather than be a benefit for consumers it could introduce confusion whereby enzymes would be labelled on the food even when they are no longer performing a function in the food as consumed and in many cases present only as an inactive or denatured residue.

4.4. Economic costs of proposed Regulation

The Food industry has indicated that the cost in preparing a dossier for evaluation by the EFSA will be in the range of 150-350k € per enzyme.

Responses from the consultation indicated that the market value of enzymes differs greatly depending on the enzyme itself and on its application. However one smaller enzyme company provided the following response:

50% of enzyme turnover is with products <500,000 €

40% of enzyme turnover is with products <100,000 €

Taking into account this data they stated that some niche products may therefore not be viable under the proposed Regulation.

4.5. 10 Year Authorisation for additive approvals

4.5.1. Impact of time limited authorisation

The proposal reflects that the Regulation and authorisation of food enzymes should remain current and therefore the positive list should only contain food enzymes which are still used. Therefore the 10 year authorisation procedure was included to enable interested parties to indicate whether enzymes are still necessary for particular applications.

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 food enzymes market. On the other hand Member States and Consumer organisations considered that enzyme approvals should be kept under some form of review to ensure that the Regulation remains current.

4.5.2. 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	2	6	
Manufacturer of enzymes	1	3	10
Importer of enzymes			2
User of enzymes		5	12
Consumer Organisations	1		
Trade association		6	7

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.

4.6. Effect on innovation and development for food enzyme

There was a varied response to this question. Some Member States considered that the proposal could encourage R&D on food enzymes. Industry predicted a decline in innovation due to the costs for the authorisation and the longer time for marketing new enzymes, which could lead to lower return of investment and consequently less R&D and less innovation.

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

However, previous discussions with industry have pointed out that a harmonised regulatory framework will provide more legal security to the enzyme producers and to the food industry and will remove uncertainty about return on R&D investments for food enzymes.

5. POLICY OPTIONS

5.1. No action (Option 1)

No action would mean that those food enzymes used as food additives would continue to be assessed for their safety and authorised under Directive 89/107/EEC. The remaining enzymes, which are used as processing aids, would continue to be put on the market without a safety assessment in the majority of the Member States.

The Member States would retain their different approaches as to the safety evaluation, approval procedures and marketing of food enzymes. Under the principle of mutual recognition food enzymes should benefit from free movement in the Single market. 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.

5.2. Non- regulatory instrument: Self-Regulation (Option 2)

A code of practice or a European Standard for the safe use of food enzymes could be elaborated by industry in combination with self-controlling actions. The use of a food enzyme could be allowed without requiring prior authorisation. For a food enzyme to be recognised as safe, industry would have to ensure compliance with the code of practice. Third Countries would have to comply with this code of practice or standard too. Abolishment of national legislation would be necessary. 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. Regulatory approach (Option 3)

The basic regulatory approach to reach the above-mentioned objectives would be to complete and harmonise Community legislation on food enzymes by introducing common rules for the safety assessment, authorisation and marketing of food enzymes at Community level.

The choice of a Regulation as a policy instrument would lead to the direct application of the rules throughout the Community of 25 Member States.

A specific act on food enzymes separately from the framework of food additives would regulate the use of food enzymes used both to have a technological function in the final food, similarly to food additives, and also those used as processing aids.

6. IMPACTS

6.1. No action – Impacts

6.1.1. Economic impact

- Food enzyme producers will bear the costs for the safety evaluation of their products only if they wish to market them in those countries where authorisation of food enzymes is required.

- The current legal uncertainty due to the differing regulatory approaches among Member States would remain, along with the current market distortions in the trade of food enzymes.

  Although the principle of mutual recognition should apply in principle, economic operators encounter certain practical difficulties associated with its application in the area of food enzymes. As recognised by the Commission in its Communication to the European Parliament and the Council "Mutual recognition in the context of the follow-up to the Action Plan for the Single Market", these difficulties appear particularly in the new technology sectors and with regard to complex products when economic operators have to deal with the requirement to observe a specific level of protection, in particular with regard to products, such as enzymes, involving considerations of safety or consumer protection. It must be borne in mind that it is for the Member States, in the absence of harmonisation and to the extent that there is still uncertainty in the current state of scientific research, to decide on the level of protection of human health they wish to ensure and whether to require prior authorisation for the marketing of foodstuffs, taking into account the requirements of the free movement of goods within the Community. The Court of Justice has held that national legislation which makes the addition of a nutrient to a foodstuff lawfully manufactured and/or marketed in other Member States subject to prior authorisation is not, in principle, contrary to Community law, provided that certain conditions are satisfied. Thus, a Member State may defeat mutual recognition of foodstuffs containing enzymes or the enzyme as such, if this enzyme or its use represents a danger to public health.

  In terms of risk assessment, Member States often start with different scientific assumptions and may require different scientific data (technical or chemical analyses or laboratory tests) which in turn may also result in trade difficulties.

- The current confusion as to whether a food enzyme is controlled as a food additive under Directive 89/107/EEC or as processing aid and subject to Member State legislation would remain causing uncertainty to industry and different interpretations between Member States.

- Food enzyme producers would continue to seek authorisation for the same enzyme in more than one Member States which is an administrative and financial burden for industry.

6.1.2. Social impact

- Differences in risk perception, safety assessment and regulation of food enzymes among Member States will lead to different levels of protection of the consumer and it will not respond to the increased interest of the consumer for food safety.

- GMO produced enzymes not covered by Regulation 1829/2003 on GM food and feed, such as microbial enzymes, will not be assessed for their safety.

6.1.3. Environmental impact

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

6.2. Non-regulatory instrument – Impacts

6.2.1. Economic impact

- Self-regulation would provide flexibility and would therefore facilitate marketing of new enzymes and ensure faster return on investment. On the other hand, food enzymes are already regulated when used as food additives by Community law and as processing aids by national legislation in some Member States. This could lead to contradictory and confusing situation for the industry with as a consequence negative economic impact.

- The application of self-regulation depends on the existence of bodies and processes to support self-regulation, including the building up of consensus amongst market players on the requirements and scientific procedures to be followed and the monitoring of enforcement. All food enzyme producers are not members of such industry bodies.

- Experience in the USA where the use of GRAS (generally recognised as safe) food enzymes does not require, by law, prior approval by FDA, shows that manufacturers prefer anyway to have official 'recognition' of their GRAS status by the authorities. For this reason FDA established a petition procedure by which manufacturers can request that the substance of interest is recognised as GRAS and subsequently included in the regulations along with conditions of use. This shows that an official recognition of the safety status of an enzyme is well perceived among manufacturers and users of enzymes.

6.2.2. Social impact

- A safety assessment, which is not carried out by an independent body, will not get the same level of acceptance from the public.
- Transparency of the procedures built in a self-regulatory system will be limited.
- An unclear legal situation will result in loss of consumer confidence about the use of food enzymes, especially with regard to enzymes obtained from genetically modified micro-organisms.

6.2.3. Environmental impact

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

6.3. Regulatory approach – Impacts

6.3.1. Economic impacts

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

The **harmonisation of the safety evaluation and authorisation of food enzymes** may result in higher upfront investments before market introduction of food enzymes due to the authorisation costs which could make enzymes more expensive. However, it must be borne in mind that some Member States already have authorisation procedures in place entailing similar costs for companies that market their products in those Member States.

On the other hand, industry will benefit from a harmonised Community authorisation procedure with defined deadlines. A "mutual recognition" of risk assessment will be achieved through the EFSA's risk assessment. By this, European producers of food enzymes could benefit by claiming safe and quality products which would in return improve the image of the food enzymes and food industries. The proposed comitology procedure and the choice of Regulation as a policy instrument will lead to timely authorisations and direct application of the rules in all Member States.

Single market trade will become easier and will increase due to the harmonised Community authorisation procedure. Trade to third countries may be affected, as enzymes would first need to be permitted within the EU before they can be traded to third countries, however, a safety endorsement may benefit trade to third countries. Similarly trade of food enzymes from third countries to the EU might be affected because of the authorisation costs.

Overall the proposed harmonisation will increase consumer confidence and create a level playing field where all food enzyme companies will benefit from the same procedure for safety evaluation and authorisation.

As described in the parallel proposal on food additives it has been decided not to revise the definition of processing aid at this stage as a result of the concerns by industry that such a move would have an impact. In relation to food enzymes the impact would have arisen from a requirement to label the presence of such enzymes affected by the change in definition. As result of the consultation, the proposal exempts from **labelling** those food enzymes used as processing aids, but requires labelling for those enzymes that are present in the food and continue to exert a technological effect.

In terms of labelling of enzymes which are present in the food and continue to exert a technological effect (currently this would include the 2 enzymes regulated under food additives legislation and in the near future it is estimated that it would affect up to a dozen enzymes) two options were considered in this proposal:

– With the first option, enzymes which are functional in the final food would be labelled on the food by the simple designation "enzyme". There is a concern that such labelling would not be informative to consumers and may lead to potential consumer confusion and concern about the addition of enzymes in the food.

– For the second option which has been included in the proposal, enzymes which are used in the same way as food additives, to exert a technological function in the final food should be labelled with their function (e.g. stabiliser etc) and specific name, instead of the general designation "enzyme". This option will have a very limited economic impact on businesses as in practice only enzymes used similarly to food additives would have to be labelled. This is similar to the current labelling requirements for food additives. For the moment, only two enzymes would be concerned, in fact, they are already currently labelled because they are additives under the current legislation. Labelling for these enzymes would only require amendment where the E number is used instead of the full name, however the effect of such change will be dissipated by allowing a suitable transition period.

6.3.1.2. Impact on direct and indirect costs imposed on businesses

There will be direct costs imposed to industry associated with the safety evaluation of food enzymes before Community authorisation is granted. This cost is estimated to be in the range of 150-350k € per enzyme. In the future, after the Community list of permitted food enzymes is established, there would also be a cost for new enzymes associated with loss of potential revenue whilst awaiting Community authorisation, however with the variability of the market value of enzymes no estimates for such costs have been provided.

In general, there are two direct cost elements:

– the cost for generating and compiling the data required for the safety evaluation of the food enzymes and

– the administrative fees related to the safety evaluation.

Member States which already require authorisation generally follow the current "Scientific Committee for Food" guidelines. Therefore the additional cost of producing studies for an EU authorisation will be negligible for those companies which market their products in those Member States. It needs also to be taken into consideration that the three big enzyme manufacturers have already many of their products approved in France or Denmark.

In relation to administrative fees, Denmark has a fee which ranges between 1,100-2,600 € while EFSA requires no fee for the moment.

It is expected that to a certain extent some of these costs may be shared across the industry (with similar enzymes being bulked together in one dossier), however for some niche products these costs will be borne by single producers. Therefore the impact of the initial evaluation costs could be more substantial for some niche enzymes used in specific food applications, depending of course on the market value of these enzymes.

The proposed long transition period, when new enzymes may continue to be marketed under current national laws until the Community positive list is established, will ensure a smooth transition to the obligatory Community authorisation.

6.3.1.3. Impact on the administrative requirements imposed on businesses

The **harmonised Community procedure** for the authorisation of food enzymes will reduce the administrative requirements imposed to the enzymes industry which currently needs to obtain approvals for the use of a new food enzyme in some Member States.

Food enzyme industry will need to comply with the proposed **labelling requirements**. In relation to food enzymes sold as such to food manufacturers and final consumers, the proposal basically codifies labelling, this resulting in the obligation to print some new labels. The impact of labelling will be mitigated by the introduction of a transitional period.

The **limited 10-year authorisation** would be an administrative measure to ensure that authorisations remain up to date and are still necessary from a technical standpoint. It was never the intention that this measure would be an onerous task and in any case it is independent from the safety evaluation of the enzymes, which will still be possible to be reviewed at any stage that safety concerns come to light. Industry however, expressed a strong view that this would be purely an administrative burden, which could destabilise the enzymes market. Considering that if there is a safety concern the Commission can act at any time, the provision for time limited authorisations is not included in the proposal. In order to address the issue of keeping legislation up-to-date, an obligation will be introduced whereby food enzyme manufacturers or users are obliged to inform the Commission and Member States when currently authorised food enzyme 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 authorisations.

6.3.1.4. Impact on innovation and research

The authorisation costs and time for marketing the food enzymes may affect R&D investments and thus innovation, especially for SMEs. Conversely, the proposed harmonised and transparent regulatory framework with well defined deadlines will give more legal security to the enzyme producers and to the food industry and will remove uncertainty about return on R&D investments for the food enzyme industry.

6.3.1.5. Impact on consumers

This proposal will have a very limited impact on households. Although the costs of evaluation seem high it is unlikely that these costs will result in any significant increases in the cost which consumers pay for food.

With the proposed labelling requirements, where enzymes which are functional in the final food are labelled with their name and function while enzymes used as processing aids are excluded from labelling, it is unlikely that the cost of foods would increase, as only a limited number of enzymes would need to be labelled. This implies no change to the current situation.

Moreover suitable transition periods will ensure that in most cases labelling impacts can be incorporated during routine label changes which companies regularly undertake.

6.3.1.6. Impact on specific regions, sectors or workers

Small enzyme producers (SMEs) may not have in some cases the resources to bear the costs for the authorisation of food enzymes, especially for small niche products. It is therefore possible that SMEs will be more affected by the proposal than larger companies. However, smaller companies are producers to a lesser degree and often buy enzymes and formulate them (i.e. mix them with other enzymes and/or with other food ingredients). For the latter they will not have to bear the cost of authorisation which will be for the producers of the enzymes instead.

6.3.1.7. Impact on third countries and international relations

This proposal will harmonise the legislation on food enzymes and will create a uniform market within the EU. Potentially the legislation may create a barrier for manufacturers in third countries until their enzymes have been included on the positive list, but this will also have a positive effect where importers are able to trade into a harmonised market.

6.3.1.8. Impact on public authorities

The Community procedure for the safety assessment and authorisation of food enzymes will move the administrative burden from Member States which have an authorisation system in place, and will allow them to direct their resources more towards the implementation of legislation and control activities.

6.3.2. Social impact

Harmonised legislation which takes into account the safety of enzymes permitted in foodstuffs will add greater assurance to consumers that the food they consume is safe to eat.

6.3.3. Environmental impact

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

7. CONCLUSIONS

On the basis of this impact assessment, the conclusion is that the policy objectives are best achieved by legislative action. There is need for harmonised procedures in the EU for the safety evaluation and authorisation of food enzymes in order to ensure a high level of consumer protection and improve consumer confidence. A harmonised legal framework will create legal clarity and consistency and thus eliminate the trade barriers resulting from the differing and fragmented legal situation in Member States.

In the interest of clarity and efficiency the best option is to propose a new regulation of the European Parliament and the Council on food enzymes, which will be directly applicable to all Member States and a separate regulation which sets up common procedures for food additives, food enzymes and food flavourings with the following objectives:

7.1. Harmonisation

The proposal offers a clear legal framework for industry in which it can continue to develop new food enzymes. At the same time the safety can be assessed appropriately through a harmonised Community procedure for risk assessment and authorisation. The inclusion of a food enzyme in the Community positive list will be considered by the Commission on the basis of the opinion from EFSA, taking into account the other general criteria (technological need, consumer aspects). For every food enzyme included in the positive list specifications, including purity criteria and origin, must be laid down. Food enzymes which are currently permitted for specific uses in wine, fruit juices and in certain lactoproteins intended for human consumption will have to comply with this Regulation and with the specific provisions laid down in the relevant Community legislation.

7.2. Better protection of the health of the consumer

One of the proposed guiding principles of the use of food enzymes is that they must not pose a safety concern to the health of the consumer. Therefore food enzymes, including those used as processing aids, will need to be evaluated for safety before they are authorised. It is proposed that the safety evaluation will be undertaken by the European Food Safety Authority in order to separate risk management from risk assessment decisions.

Additionally the proposal introduces a requirement to ensure that enzymes that would fall under the scope of Regulation (EC) No 1829/2003 on genetically modified food and feed should be authorised in respect of the genetic modification according to that Regulation prior to authorisation under the food enzyme legislation.

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. Regarding the measure to set a time limit to authorisations, after considering the concerns of industry that this would be purely an administrative burden, and considering that if there is a safety concern, the Commission can act at any time, the proposal for time limited authorisations is withdrawn.

It is however important to include a measure to ensure that authorisations remain current and promote innovation and competitiveness. Therefore, an obligation is introduced whereby food enzyme manufacturers or users are obliged to inform the Commission and Member States when currently authorised 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 authorisations.

7.3. Information to the consumer

The proposed Regulation will revise the Community provisions for labelling of food containing food enzymes and will introduce labelling requirements for food enzymes sold to the manufacturer or directly to the consumer.

During the development of the proposal on food additives 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 would create greater legal certainty. Although Member States were in general in favour of the proposed new definition, the food industry raised great deal of concerns. With the proposed clarification, many food enzymes that are currently considered as processing aids would be in the future classified as food ingredients and therefore labelled on the final food. Although the proposed labelling requirements would be light (the word “enzymes” would be mentioned without further detail), the industry expresses reservations on this approach. Industry is not against the safety evaluation and authorisation of enzymes, but they have opposition to the labelling implications. In most cases food enzymes will be inactivated due to the processing conditions (e.g. by heat treatment or changes in acidity) and not functional in the final food. Taking into account that all food enzymes will be assessed for their safety, it is proposed that food enzymes which do not exert a technological function in the finished product be exempted from labelling on the final food. On the other hand, a very limited number (currently only two, in the near future probably not more than ten) of food enzymes used the same way as food additives, to exert a technological function in the final food, will be labelled with their function (e.g. stabiliser etc) and specific name, instead of the initially proposed general designation “enzyme”. This approach would provide for a proportionate labelling of food enzymes and at the same time offer, where necessary, sufficient information to the consumer.

7.4. Transitional periods

Another point of concern during the consultation was the transitional measures. Food enzymes are already on the market in the Community. The proposal sets out a procedure for the evaluation of food enzymes and the establishment of and smooth transition to a Community positive list. The consultation pointed out that during this transition period, industry should continue to be able to develop and market new food enzymes. In order to avoid hindering innovation in this sector, the proposal now provides that during the transition period until the establishment of the Community list, new enzymes and foods produced with these enzymes may continue to be marketed under current national laws (see schematic outline in Annex).

8. OVERVIEW CONSULTATION

CONSULTATION WITH THE STAKEHOLDERS ON FOOD ENZYMES

Stakeholder organisations involved include:

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 **food enzymes**:

– 15 January 1998: first exchange of views at the Standing Committee for Foodstuffs

– 11-12 October 1999

– 24-25 January 2000

– 3-4 July 2000

– 12 February 2002

– 11 September 2003

– 22 February 2005

Other informal consultations went on with the concerned industry (above mentioned stakeholders) from 2000 to 2004.

Other consultations:

EFSA consultation 13 May 2004, 2 March 2005 and 7 July 2005.

Schematic outline

Establishment of the Community list of food enzymes