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EUROPEAN COMMISSION
Joint Research Centre



ENGLISH VERSION

ABOUT THE IPTS REPORT

The IPTS Report was launched in December 1995, on the request and under the auspices of Commissioner Cresson. What seemed like a daunting challenge in late 1995, now appears in retrospect as a crucial galvaniser of the IPTS' energies and skills.

The Report has published articles in numerous areas, maintaining a rough balance between them, and exploiting interdisciplinarity as far as possible. Articles are deemed prospectively relevant if they attempt to explore issues not yet on the policymaker's agenda (but projected to be there sooner or later), or underappreciated aspects of issues already on the policymaker's agenda. The long drafting and redrafting process, based on a series of interactive consultations with outside experts, guarantees quality control.

The clearest indication of the report's success is that it is being read. An initial print run of 2000 for the first issue (00) in December 1995 looked optimistic at the time, but issue 00 has since turned into a collector's item. Total readership rose to around 10,000 in 1997, with readers continuing to be drawn from a variety of backgrounds and regions world-wide, and in 1998 a shift in emphasis towards the electronic version on the Web has begun.

The laurels the publication is reaping are rendering it attractive for authors from outside the Commission. We have already published contributions by authors from such renowned institutions as the Dutch TNO, the German VDI, the Italian ENEA and the US Council of Strategic and International Studies.

Moreover, the IPTS formally collaborates on the production of the IPTS Report with a group of prestigious European institutions, with whom the IPTS has formed the European Science and Technology Observatory (ESTO), an important part of the remit of the IPTS. The IPTS Report is the most visible manifestation of this collaboration.

The Report is produced simultaneously in four languages (English, French, German and Spanish) by the IPTS; to these one could add the Italian translation volunteered by ENEA: yet another sign of the Report's increasing visibility. The fact that it is not only available in several languages, but also largely prepared and produced on the Internet World Wide Web, makes it quite an uncommon undertaking.

We shall continue to endeavour to find the best way of fulfilling the expectations of our quite diverse readership, avoiding oversimplification, as well as encyclopaedic reviews and the inaccessibility of academic journals. The key is to remind ourselves, as well as the readers, that we cannot be all things to all people, that it is important to carve out our niche and continue optimally exploring and exploiting it, hoping to illuminate topics under a new, revealing light for the benefit of the readers, in order to prepare them for managing the challenges ahead.

P r e f a c e



*T*his special issue of "The IPTS Report" has been devoted to research results addressing particular consumer concerns, in order to emphasise my personal commitment and that of the European Commission to better serve the European citizen.

With the progress of scientific knowledge over recent decades, one can now expect to probe more deeply the questions surrounding the production of food, the treatment of diseases, and the sustainable management and use of natural resources. One can also anticipate clarifying their impact on consumer needs, industrial practices and policy considerations.

One of the driving forces of the 5th Framework Programme for Research and Technological Development will be to help address the needs of society and to meet the requirements of the consumer, leading to future wealth and job creation, while respecting the principles of sustainable development. The approach in the context of addressing consumer concerns will be to focus on specific areas where research can potentially provide technical answers to some of the pressing questions, which would best be tackled at a European level.

Moreover, the Joint Research Centre of the European Commission, whose workprogramme already includes a specific line of action devoted to the consumer protection area, has created the Institute for Health and

Consumer Protection. This new institute will enhance the scientific and technical knowledge available to the EU Commission services and to all Member States authorities on hazards and risks, caused by products and processes of various kinds, to which the European citizen is exposed. The European Commission is paving the way towards a genuine "European research area", where European laboratories, universities and companies devote a significant part of their resources to protect the consumer, in other words to promote European research at the service of the citizen and European competitiveness in a global framework.

Olsson

THE IPTS REPORT C O N T E N T S

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SPECIAL ISSUE: RESEARCH AND CONSUMER ISSUES**4 Editorial****6 The Institute for Health and Consumer Protection: A New JRC Institute serving European Citizens**

Under the EU Fifth Framework Programme for research the IHCP will be responsible for a range of health and consumer concerns as part of the overall aim of serving Europe's citizens. Its aim will be to provide the scientific and technical expertise necessary to give policy makers independent advice on issues relating to food, pharmaceuticals, chemicals, etc.

9 Improving Consumer Protection: Support for Food Control

Consumer confidence depends not only on proper labelling but also on the fact that this is backed up by adequate controls to avoid food-related fraud. The JRC, in conjunction with other centres across Europe, is working on developing the necessary analytical methods and dissemination of both techniques and test data to the food laboratories responsible for controls.

15 Future Technologies, Changing Consumer Decisions and Labelling Requirements

The range of products available to consumers is constantly increasing, sometimes making choices harder, particularly in view of growing health concerns about food. Labelling will only be a help if it gives consumers the information they want in a way they can interpret, and this requires the engagement of all stake-holders as well as efforts to raise awareness and educate consumers.

20 Biotechnology and Health Care: Consumer-Related Aspects

The various technologies included under the rubric of biotechnology are likely to have a major impact on the health care market in the coming years. As new products become available issues relating to assessing their worth and how to channel demand will become yet more pressing.

26 The Supply of Information to the Consumer: When More is Actually Less

In the electronic market place consumers are using increasingly sophisticated tools to find products matching their requirements whilst retailers are using more sophisticated ways to profile their target customer groups. The overload of information for online consumers in a rapidly expanding Web market and concerns about the protection of data being gathered about them are two of the issues raised.

EDITORIAL

Fabiana Scapolo and Anette Schmitt

Research and the accumulation of knowledge concerning the impact of technology on consumer issues are important factors for policy makers to take into account in this area.

This special issue of The IPTS Report is an introductory presentation of the citizens orientation of European research policy as prominently featured in the Fifth Research Framework Programme of the EU Commission.

In October 1998, the Joint Research Centre (JRC) of the European Commission set up the Institute for Health and Consumer Protection (IHCP) in Italy. This special issue on S/T and consumer issues is partly a response to this institutional innovation, whose mission is to increase the scientific and technical knowledge of EU Commission services and of Member States Authorities on hazards, exposure and risks, caused by products and processes of various kinds and to which European citizens may be exposed. The first two articles of this special issue present the activities of this new institute.

While the value of information has risen, the cost associated with the time needed to become well informed has also increased. With the enormous proliferation of product alternatives, information has become ever more important to consumers. The private and public benefits from

truth in labelling and advertising imply therefore a continued role for EU regulation of information about the attributes of consumer goods. With the increasing use of health as a marketing tool, the amount of nutritional information on food labels, for instance, has sharply increased in recent years. One article of the report therefore discusses nutrition labelling, which has recently become mandatory on processed foods within the European Union but which continues to be one of the most high profile and controversial aspects of food legislation. In response to this debate, the Commission has launched in October 1998 a "European food safety campaign" which is to run in all 15 European Union countries.

Among the practical tools for implementing labelling, control laboratories in all Member States are expected to use harmonized and validated methods, analytical standards and mutually recognized approaches to analytical quality assurance. One article argues therefore that it is essential to devote adequate financial and scientific resources to the necessary practical measures needed to bring this about and to enable control laboratories for effective enforcement of safety and labelling regulations.

The next article focuses on the potential biotechnology has to produce wide-reaching social and economic impacts. In fact, the ever increasing range of potential applications opening

up to biotechnology suggest it is likely to pervade many aspects of life in the future, also by improving the quality of life in many areas. In particular, an accelerated rate at which new pharmaceutical projects could become available may require policy responses in a number of areas.

The final article deals with the impact of novel Internet-based technologies used to identify high-quality products, better services and prices. Gradually consumers are becoming more qualified in gathering and analysing market related information in the shortest time with the effect that too much information to scan through makes selecting more difficult. Targeted advertising raises questions of privacy rights and moral concern about how information should be used. Measures ought to be studied that would

educate the consumer early on, as to how to combat Information Overload, as well as keep an eye on key actors and the way in which they might exploit their dominant market position.

Finally, the citizen is the focus of many EU activities. On 22 September 1998, seven Directors General (i.e. DGs V, X, XV, XVI, XXII, XXIII, and XXIV) signed the agreement on a major information initiative '*Europe Direct, Permanent Dialogue with Citizens and Business*'. 'Europe Direct' is a service that aims giving a user-friendly direct access to information and advice about the European Union and citizens' rights in the Single Market. This service will operate in all Member States through the Web and free phone numbers, whereby the public will be allowed to submit queries and receive replies in their own language.

The Institute for Health and Consumer Protection: A New JRC Institute serving European Citizens

Livio Manes, *IHCP*

Issue: The Joint Research Centre (JRC) of the European Commission has recently been supplemented by a new institute, the Institute for Health and Consumer Protection (IHCP). The mission of the IHCP is to increase the scientific and technical knowledge among EU Commission services and the relevant authorities in Member States concerning hazards arising from products and processes of various kinds to which European Citizens are potentially exposed.

Relevance: The duty to "serve the citizen" guides the political and legislative action of the European Commission, inspiring policies meant to address the issue of dangerous environments, products and events which may jeopardise health and quality of life. The scope of the IHCP is to help these policies, by means of scientific and technical support actions.

Analysis

Consumers are potentially at risk from many sources; food, drink, cosmetics, etc. And apart from health risks, counterfeit or adulterated goods may have negative effects on the quality of life

The field that IHCP is called upon to monitor and explore is very broad. It is important for Europe to have a structured and predictable health and consumer protection system (with the repercussions this may have on trade). In fact, the image of the European Union has not only to be defended, but also enhanced given its role as one of the "trademarks" of our European culture.

Though the field is wide, the IHCP must find the best way to employ its resources for this purpose. The fact that the IHCP is part of the Joint Research Centre (JRC) of the European Commission is an important feature. The mission of the JRC was defined as being "the reference

centre of science and technology of the Union", i.e. an institution providing sound EU-policy oriented research supporting the management of change in our society.

Among their everyday purchases consumers may happen to come into contact with substances which, for one reason or another, pose a threat to their health. Such substances may form part of food, drink, cosmetics, and even ornaments. This can have serious consequences, especially for children. Also, the marketing of non-prescription drugs or inadequately defined chemicals can constitute a threat. Even without immediate damaging consequences to health, counterfeit or adulterated products may fail to live up to consumer expectations and even have negative effects on the quality of life. With the increasing

impact of biotechnologies in agriculture and in food production, it is essential to ensure genetically modified organisms (GMOs) do not give rise to unacceptable hazards resulting from their deliberate or accidental propagation. But also, the consumer needs to be helped to perceive promising and highly beneficial technologies correctly in order to make informed judgements. In all these examples, scientific and technical support means performing careful analysis of the products and their compatibility with the biosphere, and this involves assessing not only immediate risks but also the long-term consequences of a prolonged exposure. Another interesting research avenue being pursued is cellular testing, which seems to offer a promising biotechnological tool to reduce the need for costly and less ethically acceptable animal testing.

Health needs to be enhanced by making available advanced methods for diagnosis and therapy, especially for the early detection and treatment of widespread diseases such as cancers, cardiovascular diseases, and neurological disorders. There is a need to harmonize and increase the reliability of most medical methods as well as to make it possible for citizens and health-care services to support their cost. The present abundance of biocompatible body inserts and implants, for instance, calls for studies on their reliability and on their expected lifetimes.

Both policy makers and the public should be constantly kept abreast of current and emerging issues in these fields, whilst seeking to avoid sensationalism. Hence, there is a need for an accredited database containing critical assessments produced by the competent European Authorities. Europeans need to see these assessments backed by the scientific and technical support of a body of scientists which is independent of commercial and national interests, and this is a role which the IHCP aims to play.

The mission of the IHCP must be achieved through the commitment of its entire staff, who need to bring their expertise and skills to bear on their two main functions. On the one hand, the IHCP must fulfil its role as a Commission service maintaining constant and dynamic communication with policy makers: these include EU Directorates General as well as the National Regulatory and Healthcare Organizations and Industries in the Member States. The IHCP's work programme must therefore be demand-oriented and its activities must always be well attuned to the EU political agenda in its fields. On the other hand, the Institute needs to be recognized by the S&T community in Europe as a highly reputed partner and its work requested for collaboration in and co-ordination with extensive networking. This will underwrite the IHCP's credibility and gain acceptance for it as an indispensable link to the EU decision-making process for all technical problems. Therefore, the IHCP must be able to demonstrate its scientific and technical excellence and its ability to judge emerging products and systems. The fact that it hosts a multidisciplinary team of scientists and technicians ensures it has the high quality, flexibility, and scientific credibility necessary to represent the interests of the citizens of the Union, and also the ability to form an important part of the framework of the much larger and highly qualified interdisciplinary environment of the European scientific and industrial community.

The IHCP's mission requires it to respond in a flexible and appropriate way to demands as soon as they arise and also for it to participate in ongoing scientific and technical developments. This can only be achieved if an adequate research effort is undertaken at the Institute. Obviously, this research cannot cover all aspects of these complex fields. Rather, a selective effort must be made so as to obtain maximum benefit from the particular skills, which are present in, or can be acquired by, the Institute.

Health needs to be protected by making available advanced diagnostic and therapeutic methods, especially for the early detection and treatment of widespread diseases

The Institute for Health and Consumer Protection is intended to meet these needs by offering technical and scientific expertise independent of particular commercial and national interests

The new institute will channel and develop existing activities created under the Fourth Framework Programme. Also, it will work in collaboration with other institutes under the umbrella of the JRC

The IHCP comprises a Food unit and two dedicated information units: "Support to Pharmaceutical Regulatory Activities" and the European Chemical Bureau ("ECB" Unit)

About the author

Livio Manes is a physical chemist and has worked at the University of Rome and the University of Michigan. He has worked at the JRC since 1964 where he is unit head of the Institute for Advanced Materials and advisor to the Director of the Institute for Consumer Protection and Health and is responsible for its general strategy under the Fifth Framework Programme. He has also carried out research for the ITU (Institute for Transuranium Elements) in solid state physics, theoretical thermodynamics, and nuclear technology.


In the Fifth JRC Framework Programme the IHCP is set entirely within Action I, "Serving the citizen". The IHCP does not stand alone but is envisaged as forming part of a cluster with other JRC Institutes. In particular, the IHCP will collaborate with the IPTS, which will provide a forward looking, policy relevant assessment of forthcoming issues of relevance for consumer protection, as well as rapid *ad hoc* emergency support to Commission services drawing on the expertise of the IHCP. Furthermore, the new institute has not been born in a vacuum, most of its activities in fact stem from work already started as institutional and/or competitive support to Commission activity during the Fourth Framework Programme.

The IHCP Food Unit has competence for the analytical chemistry necessary to examine consumer-product safety and quality. It continuously develops new validation methods, through comparison, confrontation and inspection of results within appropriately constructed European networks and it has started action in the field of genetically modified organisms (GMOs). The European Centre of Validation of Alternative Methods (or "ECVAM" Unit) is a laboratory of recognized prestige performing research on biocompatibility and on the issue of substituting animal testing with cellular testing strategies. The "Biocompatible Materials and Cyclotron Unit" provides a necessary background in physics, physical chemistry, numerical modelling and design engineering.

Finally, the two dedicated information Units - "Support to Pharmaceutical Regulatory

Activities" and the European Chemical Bureau ("ECB" Unit) - manage the link between the database and policymakers, not only from a technical view point, but also in the general framework of consumer policy.

Outlook

The IHCP's existing potential already includes a significant share of the disciplines needed for its work and this may be complemented with other areas through networking. Teething problems may naturally arise when integrating so many different interests, cultures and languages. Nevertheless it is the IHCP's task to overcome them, and it is confident of being able to do so within the Fifth Framework Programme. The IHCP is aware that only in this way will it be able to provide the European Commission with the high quality, flexible, coherent, (albeit small) **scientific force** that Europe deserves. In the long-term its scope will take in the monitoring, and where possible reduction, of health hazards and so it will come to play a part in improving the quality of life. To do this its status as a European Commission body, independent of commercial and national interests, is essential. In addition, the IHCP work programme is demand-driven, responding to the needs of society, and to support EU policies. This can be achieved through dialogue with national and international regulatory authorities, biomedical industry players, and networking with the medical world. This new shared mission defined for the JRC will also be the hallmark of this new Institute. 

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Improving Consumer Protection: Support for Food Control

Elke Anklam, *JRC*, John Gilbert, *CSL Food Science Laboratory (UK)*

Issue: There is a need to support food control in the EU and to ensure that the practical tools for implementing regulations are available to control laboratories in all Member States. The necessary 'tools of the trade' are validated methods, analytical standards and mutually recognized approaches to analytical quality assurance.

Relevance: Today, European regulations are frequently implemented without the necessary practical measures being available to enable effective enforcement. It is essential to devote adequate financial and scientific resources to remedying this situation.

Food Control in the European Union

Food scares in Europe have eroded consumer confidence in food and the food supply. This has made the need to ensure and to demonstrate adequate food control measures particularly pressing. There has been considerable progress in the European Community towards establishing mutual recognition in the food-control sector with, for example, the Additional Measures Food Control Directive which will be fully implemented in 1998. This requires food control laboratories to be EN45000 accredited and to participate in proficiency testing. Whilst the practical means exist for laboratories to put in place the quality systems stipulated by this Directive, there are additional requirements concerning the use of validated methods and internal quality control requirements which can be more difficult to meet. Validation of analytical methods by a minimum of

eight laboratories (as required by international harmonized protocols) is a time-consuming and an expensive process. Policy makers often have to confront a situation in which analytical methods have not been fully validated and there is a lack of analytical standards or suitable reference materials. The European Commission has taken several initiatives to try to improve this situation. Since 1991, the European Commission's Joint Research Centre (JRC) has given increasing technical and scientific support to European regulatory actions in the area of foods, foodstuffs and other consumer goods. Today, it plays an important role in method development, harmonization and validation. In addition, the European Standards Measurement and Testing Programme (SMT) has funded a number of projects on method development, method validation, production of reference materials and dissemination of information to assist food control laboratories in the food safety and food

Since 1991 the European Commission's Joint Research Centre has given increasing technical and scientific support to European regulatory actions in the field of foodstuffs and other consumer goods

The forthcoming harmonized directive on mycotoxins sets the concentration limit below the threshold for which validated analytical methods are currently available

Laboratories from a number of Member States are working collaboratively on mycotoxin testing to meet this need

Over the next few months the laboratory intercomparisons in four mycotoxin work areas will be carried out, covering a total of ten different food matrices

authenticity sectors. Some examples of these support activities performed for the benefit of the European consumer such as validation of test methods, dissemination of information, testing methods for controlling food-related fraud and testing the presence of genetically modified organisms (GMOs) are illustrated below.

Validation of methods of analysis for mycotoxins

Mycotoxins are toxic fungal metabolites which can be present at low levels in a wide range of foods. Aflatoxin B₁ for example is a known human liver carcinogen and can occur in cereals such as corn, nuts such as pistachios and dried fruit such as figs. Different Member States have regulatory limits which range from 1 to 25 µg/kg (ppb) in specified foods but which will shortly be harmonized in a Community Directive setting a limit at 2 µg/kg for aflatoxin B₁ and 4 g/kg for total aflatoxins. However, there are so far no validated analytical methods for such low concentrations.

Anticipating this difficulty the Standards, Measurement and Testing (SMT) Programme has funded a project (CT96-2045) to validate methods of analysis for aflatoxin B₁ and total aflatoxins in peanut butter, pistachios, figs and paprika; aflatoxin M₁ in liquid milk; ochratoxin A in barley and roasted coffee and patulin in apple juice. The project, which began in October 1996, is being co-ordinated by the UK Ministry of Agriculture, Fisheries and Food, and involves ten partners from six Member States including the JRC.

It is important when undertaking collaborative trials to use materials as close as possible to real foods and that are naturally contaminated with the substances in question. In this project, the naturally contaminated materials were obtained by taking a selection of samples from those being analysed as part of the normal EU commercial import checks.

The target levels of contamination were obtained by careful blending of control (uncontaminated) materials with mycotoxin contaminated foods. It is essential to produce homogeneous materials for intercomparison purposes and considerable effort goes into grinding, mixing and homogeneity testing. For example, peanut butter was milled to ensure that no particulate material remained in the finished product, and oil separation was avoided by the addition of lecithin.

Laboratories experienced in the analysis of mycotoxins covering a range of Member States from Government, academia and industry sectors have volunteered to participate in the intercomparisons. Some 16 laboratories are taking part in the aflatoxin B₁ intercomparison. Laboratory personnel have been assisted in preparing for the trial by means of a training video specially filmed for the project, analysing practice samples and participating in a training Workshop. Copies of the video (currently in English but also being translated into French, German and Spanish) which covers the analysis of aflatoxin B₁, aflatoxin M₁, ochratoxin A and patulin can be obtained from the authors.

Over the next few months the laboratory intercomparisons for the four mycotoxin work areas will be carried out covering a total of ten different food matrices. On completion of the trials the validated methods with associated performance characteristics obtained from the intercomparisons, will be passed to the European Committee for Normalization (CEN) for adoption as European Standards. The CEN Standards will be recognised by the European Commission as Official Methods and will thus become available to food control laboratories as referee methods. The project will fulfil international requirements for validation and the methods will also be passed to the International AOAC (Association of Official Analytical Chemists) for adoption.

Dissemination of information through the Internet

Some Directives (e.g. Directive 90/128 EEC and amendments) controlling plastic food packaging materials are complex and detailed. Their objective is to make sure that only named substances can be used in the manufacture of plastics (positive list). Additionally the residual amounts of certain substances in the plastics are controlled and the amounts permitted to migrate into food are restricted. Several hundred frequently obscure substances are controlled through the positive list and tens of substances have control limits.

The analysis of food packaging materials and migration testing are specialized areas which are outside the normal sphere of activities for many food control laboratories. Therefore this area in particular is one where support for food control is essential. The JRC is preparing a European database of reference substances containing background information, characteristic spectra and other physical chemical data in three stages: 1. Characterization of new substances for use as a constituent of food contact materials when technical dossiers are submitted to the Commission of the European Communities for authorization, and comparison with given data; 2. Hosting of the existing reference collection; 3. Implementation of solutions for public access to written materials (i.e. via the World Wide Web) concerning food contact materials such as Directives, practical guides, synoptic documents, methods of analysis and relevant information on substances used in materials in contact with food. The SMT Programme has financed a number of projects involving collection of reference substances and generation of appropriate spectroscopic data such as retention indices, nuclear magnetic resonance (NMR), infra-red and mass spectra. This information on monomers and starting substances

and on plastics additives has been published in the form of reference books. Another SMT project has generated a number of analytical test methods for determining residual monomer levels in plastics and also monomer concentration in food simulants after migration testing.

This project carried out jointly by the JRC and the Central Science Laboratory of the UK Ministry of Agriculture, Fisheries and Food (MAFF) aims to disseminate this information as widely as possible by making it available on an Internet web-site. The site comprises an introductory page followed by a searchable listing of all of the substances for which information is available on the site. For each substance there is a datasheet page available giving general information such as CAS number, chemical structure, molecular weight, regulatory limits etc. The web-site facilitates rapid downloading of suitably formatted files. For each substance, where available, the site provides its mass, infra-red and NMR spectra and methods of analysis. When the database has been completed, the JRC will have long-term responsibility for updating and maintaining it. This oft-forgotten aspect of the long-term maintenance of a web-site of European interest is seen as another important role for a European institution.

Complementing the web-site is a collection of reference substances from which the spectroscopic data were obtained. These substances are in most cases commercial samples which cannot be purchased from normal chemical suppliers. Each has been spectroscopically characterized and purity tested and is being made freely available as an analytical standard to food control laboratories and other interested parties. Samples of all new substances submitted to DGIII for authorisation are now lodged with the JRC thereby ensuring this unique reference collection is maintained in up-to-date condition.

Plastic materials used for food packaging are regulated via lists of often obscure substances. Migration testing is highly specialized and often beyond the normal capabilities of food control laboratories

The JRC is preparing a European database of reference substances for use as food contact materials with a full range of technical data

Analytic data required by laboratories will be made available over the Internet in downloadable form from a database maintained by the JRC

The European Office for wine, liqueurs and spirits (BEVABS) maintains a wine data bank with a range of technical data that can be used to authenticate wines and detect adulteration

The JRC is working on reliable analytic tests for cocoa-butter equivalents in chocolate products

Developing methods to control food-related fraud

Adulteration of wine by the addition of sugars of different botanical origin (i.e. non-grape) to increase the alcohol content together with watering of wine are the major problems in the wine-producing countries. Nuclear magnetic resonance (NMR) and isotopic-ratio mass spectroscopy (IRMS) are able to detect such wine adulteration with a high degree of certainty when used with information from an appropriate data bank. The European Office for wine, liqueurs and spirits (BEVABS) was created at the JRC officially in 1993 in agreement with DG VI of the European Commission. The main purposes of this office are to provide laboratory services to the EU and its Member States and to maintain an EU wine data bank containing the results of NMR measurements and all information concerning the location of the vineyard, the type and growth of grape used in authentic European wines since 1991. This work is carried out in collaboration with specialized laboratories in the EU Member States (in wine producing countries). The wine data bank is currently being enlarged by data on other naturally stable isotopes (^{13}C , ^{18}O). The NMR method is based on the determination of the isotopic ratio of deuterium/hydrogen at the various sites of the ethanol molecule and this allows the identification of the botanical origin of sugars present in the original must before fermentation. Additional information concerning sugaring and watering can be obtained using the IRMS method. Both methods can also be used to analyse liqueurs, spirits, fruit juices and sugars after fermentation and distillation.

D-malic acid has been claimed not to occur in nature and is considered to be evidence of adulteration of fruit juice. Recent work has demonstrated that this is no longer valid for wines. The presence of artefacts in the European official

method for the determination of D-malic acid in wines has also been found. The JRC and Member States laboratories are re-examining the official method and the assessment of the actual levels of natural D-malic acid in wines.

Due to the harmonization of the chocolate Directive 73/241/EEC there is an urgent need for improvement or development of methods which allow quantification of 5% vegetable fats (other than cocoa butter) in final chocolate. Due to the natural variation of cocoa butters as well as to the fact that the vegetable fats used in chocolate production (cocoa butter alternatives) are very similar in their physical and chemical composition to cocoa butter, quantification is a very difficult task. The lack of reliable analytical methods to detect and quantify these vegetable fats (so-called cocoa butter equivalents) in mixtures containing cocoa butter and in chocolate, is likely to cause difficulties for the national authorities responsible for checking compliance with legislation. The JRC is developing a suitable analytical method in collaboration with several laboratories from EU Member States. Various analytical tools are under investigation for determination of triglyceride-, fatty acid-, vitamin-, sterol- and trace element compositions using multivariate statistical data evaluation. Preliminary results revealed that a single analytical method might not be sufficient to tackle all problems. However, the results already available from this project are indicating that a combination of different analytical techniques might result in an approach that allows the reliable determination of cocoa butter equivalents. Final results are expected to be available at the beginning of 1999.

The Council Directive 74/409/EEC on the harmonization of the laws in the Member States relating to honey lays down common rules for its composition and manufacture. The Commission

has adopted a proposal to amend this Directive providing for the name "honey" to be supplemented by information referring to the products' botanical (floral or vegetable) or its geographical (regional or territorial) origin. The lack of reliable analytical methods to permit the identification of the botanical or territorial origin makes the verification of compliance with labelling a very difficult task for authorities in the Member States. The wide variety of plants from which honey derives and the natural variation of plants (the influence of climate and geographical conditions) makes it very difficult to determine the botanical origin of honey, let alone relate this to a particular geographical location.

Whereas determining isolated parameters such as 5-hydroxymethyl furfural (HMF), residues, enzyme activity, moisture, nitrogen and monosaccharides and disaccharides in honey does not provide significant information about the botanical and geographical origin, there nevertheless seem to be some suitable methods based on analysis of specific compounds and/or on multi-component analysis. Mostly, such methods give an indication of the botanical origin by investigating flavonoid patterns, pollen distribution, aroma compounds and special marker compounds. There are some other profiles of components which could probably be used for the detection of the geographical origin (e.g. oligosaccharides, amino acids, trace elements). A combination of methods could be a promising approach for proving authenticity, especially, when up-to-date statistical data evaluation techniques are applied.

The JRC is coordinating a project on the development of suitable analytical methods in this context. Several participating laboratories from EU Member States are applying the most promising combination of methods: analysis of trace elements, oligosaccharides, amino acids,

organic acids, DNA analysis, pollen analysis, flavonoids, aroma compounds and stable isotopic ratios. The results are expected in spring 1999.

Detection of Genetically Modified Organisms (GMO) in Foods

Council Regulation (EC) No. 1139/98 concerning the labelling of certain foodstuffs produced from genetically modified organisms (GMOs) indicates that at this stage the presence in foods and food ingredients of protein or DNA resulting from genetic modification constitutes the criterion which best complies with the requirements set in the Regulation. There is an urgent need for adequate validated analytical methods.

The evaluation of a screening method (direct method for detection) based on DNA analysis by means of polymerase chain reaction (PCR) has been carried out by the JRC. The principle of the method is the detection of certain promoter and terminator sequences which are present today in most GMOs. This method has been validated in 1998 by 29 laboratories in many Member States of the EU together with Switzerland and the USA. Standard materials (flours from corn and soy beans) have been prepared in collaboration with IRMM Geel and are already available to the public.

The JRC will investigate in collaboration with EU Member States' laboratories the applicability of screening methods and quantitative methods for GMO determination in processed food.

Benefits to the Consumer from Community Funding

An article such as this can only present a snapshot of the range of activities being funded by the European Community in support of food control. Large projects such as method

Honey is another example of a product whose botanical or territorial origin is hard to determine

Tests are being developed to detect the presence of GMO-derived matter by means of their characteristic sequences in the DNA

The availability of adequate analytic tests is an essential part of ensuring compliance with labelling regulations, and the JRC's work is indicative of the importance of a Europe-wide approach


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validation for mycotoxins could not be undertaken without central funding or the involvement of expert laboratories from a number of Member States. The dissemination of methods of analysis and of spectroscopic data via the Internet illustrates the essential role that the JRC can play in the food control sector. The maintenance of a reference collection of analytical standards for free distribution to food control laboratories is another example of a centralized Community activity. The JRC's role in consumer protection is wider than just food safety and the example of co-ordination of method development for authentication of honey and chocolate exemplifies a more speculative research activity, again involving expert laboratories from a number of Member States. The consumer benefits in being secure in the knowledge that food on sale is safe and that compliance with labelling is being monitored. These examples illustrate how European Community funding can translate into real improvements in consumer protection.

The Future

Over the next few years there will be increased harmonization across Europe in the food control sector. This will translate into the unification of control measures as well as into continued efforts to bring food control laboratories in the EU to a common high standard. At the same time, we can expect more technological developments in the food control sector relying on centralized and rapid information systems to ensure and improve consumer protection. To make this a reality in the future, continued support is needed. The role of the JRC will be pivotal to these developments. There will be a continued need for co-ordination of the process of validation of methods of analysis. In addition, there will be a continued and growing need for centralized dissemination of support to the food control sector. Finally, as we have shown with the example of GMOs, there will be a permanent need for rapid central initiatives to ensure consumer protection, something which should be maintained as a high priority. 

Keywords

mycotoxins, wine, honey, chocolate, GMOs, food packaging, authenticity, analytical methods, Internet

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Future Technologies, Changing Consumer Decisions and Labelling Requirements

Anette Schmitt, *VDI-TZ*

Issue: Consumer behaviour is much more volatile and much less predictable than was the case 20 years ago. The trend towards individualisation is increasingly significantly and is generating demand for more differentiated and more rapidly changing product information.

Relevance: With the enormous proliferation of product alternatives, information has become ever more important to consumers. At the same time the value of information has risen, the cost associated with the time needed to become well informed has also increased. The private and public benefits from truth in labelling and advertising imply a continued role for EU / government regulation of information about the attributes of consumer goods.

Introduction

One major European supermarket chain estimates that the number of food items in a typical retail store increased from 550 in 1954 to more than 10,000 only 40 years later (Sainsbury's, 1995). Eating in the home has become more informal and individual and less predictable (King, 1983). A survey in France indicated that time spent each day eating at the table decreased from two hours 30 minutes in 1965 to one hour 20 minutes in 1995 (INSEE).

Aspects of safety, the environment, energy, performance, quality, services, and information technology, greater mobility, double incomes, new sales outlets, longer opening hours and a larger selection of ready-to-eat products will

magnify this effect and this has implications for patterns of technological development. Biotechnology, separations technology, sensor technology and modern information technology are some of the relevant technologies in this context. Electronic shopping could achieve a share of about 10% or even 25% in total food sales in the Western world by the year 2005 (1). Virtual shops are already operational on the Internet, although at the moment many of them serve primarily as a source of information for the consumer which - in turn - influences the choices available to consumers, as well as their knowledge and buying habits.

Consumers are bombarded with many different messages which vary over time and between the interest groups. With the increasing

Consumers are bombarded with messages concerning health and food which may often be presented in a way that is too complex or technical for them to be able to understand

Labelling is seen as a way of allaying fears concerning issues such as GMOs, for instance, but unless labels are well designed they can simply create more confusion rather than convey information

The Commission has launched a food safety campaign designed to engage consumers and consumer groups in member states in creating shared responsibility for food safety

use of health as a marketing tool, the amount of nutritional information on food labels, for instance, has sharply increased in recent years and nutrition labelling has recently become mandatory on processed foods within the European Union. Nutrition labelling is based on the premise that the information presented will help consumers apply general nutrition principles and the national nutrient goals when purchasing food. However, many consumers neither understand nor use much of the nutrition information on food labels when making food-purchasing decisions. The limited impact of this information may be attributed to its technical nature, complexity and numeric form, which make it difficult and time-consuming to process.

The trouble with labels is that unless they are properly designed they can create as much confusion as they convey information. They may be meaningless without explanation in some environments and cultures.

In 1997 the Commission carried out the **Eurobarometer survey** to look specifically into consumer issues. One of the points that came out strongly from that study was consumers' concern about the safety of food products. The results varied between Member States but on average 68 per cent of consumers expressed concern about food safety. The importance of food safety for European consumers was further confirmed during the chat-line Commissioner Bonino organized on 5 November 1997. Those concerns have been amplified by many recent stories in the media which have for example referred to 'mad cow disease' (BSE), E-coli, Salmonella and genetically modified organisms in food.

The placing onto the market of genetically modified products over the last 12 months has, furthermore, led, in some countries, to even greater concern amongst consumers and consumer groups about what they are eating and

how safe it is. Their concern has focused in particular on the absence of specific labelling which could enable informed choices to be made. In addition, there is unease about the limited experience with this new technology, with the perception that current scientific claims may, in certain cases, be disproved in the future.¹

The debate surrounding food labelling centres on two main aspects; firstly the provision of consumer information to enable consumers to make informed choices concerning product quality and characteristics; and secondly, the information that could be relevant from a food safety point of view.

The Commission therefore decided to devote the 1998 **consumer policy information effort** to the issue of food safety and consumer health, and then to extend their effort into 1999. In response to a specific demand from consumers for more information, in October 1998 the Commission launched a "European food safety campaign" which is to run in all 15 European Union countries. (2) The campaign, whose slogan is "Food safety is a shared responsibility; the responsible consumer is informed and active", aims to inform and educate the consumer. Consumer associations have been closely involved in planning and implementing the campaign in each Member State. It also ties in with the Commission's concern to help reduce the frequency and impact of food poisoning in Europe, and is particularly innovative in that it provides for a large measure of decentralisation, with the creation of national consortia bringing together all those involved in the food production chain: farmers, processors, retailers and consumers.

In the meantime, labelling continues to be one of the most high profile and controversial aspects of food legislation, even though the labelling regulations do not apply to food

additives, and this can be quite significant. There have been calls for more detailed information to be given to the consumer, which would put ever-increasing pressure on manufacturers, who do not want to be continually re-labelling their products and often find it a major challenge to fit all the information required under current regulatory provisions on the label.

Discussion

Product labels can be of great value to consumers in allowing them to make more informed choices between goods and services offered. For this to function optimally, the EU should examine and evaluate the effectiveness of product labelling, and consumers would need to participate in these investigations if they are to get the product labelling they want. If there is clear evidence that a particular product is likely to be harmful, or if the available evidence is inadequate to provide sufficient guarantees of safety then that would be an issue of concern to European policy makers. It is known that there are persistent, deeply held differences of opinion which engender mixed reactions among consumers, industry and retailers, and this may be why one needs to be cautious about issuing policy statements.

The European Commission's Green Paper on the general principles of food law in the EU recognizes that labelling has, thus far, been approached on a narrowly functional basis. The question is now being asked as to whether the right kind of information is being given to consumers, or whether some of the information currently required is inappropriate.

Regulators must consider questions such as:

- what role does health play in evaluating the acceptability of new foods and ingredients?
- in which areas does the consumer need greater convenience?

- how is it possible to get clear evidence that a particular product is not likely to be harmful?
- how important is sensory perception and what role do situational factors play?
- how should we handle communications relating to new technology (and under what conditions can there be consumer acceptance)?
- how do we pay sufficient attention to consumers' perception of risk in relation to food (consumer concerns)?
- what will be the effect of the social undercurrent demanding that such aspects as the environment and animal welfare be considered in the regulation of the production process?
- what are the implications of electronic commerce for production and distribution and are consumers ready for this?
- how should labels be designed such that they would not set up direct or indirect, deliberate or accidental, barriers to trade, and so that they can give as immediate an idea as possible of the content, the effects and the qualities of a product?

What is certain is that labelling will continue to be one of the key aspects of food legislation, and it continues to be important for manufacturers and retailers to be aware of potential developments that could have an impact on the demand for their products.

From the **consumers' point of view**, an appropriate regulatory regime should provide the confidence that adequate safeguards are in place, especially where foods using new genetic technologies are involved. The public first and foremost wishes to see a full application of the precautionary principle which would allow prompt detection of any adverse effects not currently foreseeable. It requires that novel foods, genetically modified organisms and food ingredients should not be labelled in a misleading way.

Labelling continues to be a controversial issue. Many manufacturers already find it difficult to fit all the information required on their product label

It is now recognized that the approach taken to labelling to date has been too narrow and that a broader range of issues need to be addressed so that consumers are given the information they want whilst avoiding the creation of artificial barriers to trade

The European food safety campaign could help improve the situation by giving consumers help in understanding the information on labels

From **industry's point of view** labelling requirements can be prepared, adopted or applied in such a way that they become trade barriers. Ways to affix labels, the information required, the size of the labels, the languages required, when and how to label are factors which must not be allowed to become so demanding that they create unnecessary barriers to trade. Hence, legislation should be of sufficient flexibility so as to be conducive to innovation and to allow for the successful commercial development of technology.

Outlook

The existence of advice and labelling *per se* is, therefore, not a sufficient condition for consumers' safety. Consumers must understand the labels in order to make the recommendations work. Labelling regulation will only be effective if linked to a complementary programme of consumer education and advice and the restriction of marketing opportunities from 'umbrella claims'.

Implications for a policy strategy might be to explore the relative impact of health warnings,

dietary advice, and negative and positive media coverage upon the sales of food products.

The new 'European food safety campaign' could help to improve the present situation by supporting the consumer in understanding the information given on the labels. The programme's intention is that: "If there is a problem, [the consumer] contacts the consumer associations and/or competent authorities. In the majority of Member States, the approach will be to highlight the importance of following the instructions given on the labels and abiding by the basic rules of hygiene." (2)

Hence, whatever the true nature of an optimum label might be, policy makers must explicitly take stock of what is attainable in terms of lifestyle, technology and the economic environment of the markets. Policy makers, bio-technologists, food scientists and social scientists will need to work in close co-operation to share information and to achieve a better understanding of the biological and social processes. However, as the case of genetically modified food demonstrates, this is no simple task since its health adverse effects are being hotly disputed. ●

Keywords

consumer protection, food and nutrition, food labelling, food safety, decision supporting information

Note

1- The Commission has spent the last twelve months reviewing proposals on the issue of how to label foods and food ingredients derived from GMOs, despite the long-awaited adoption of Regulation (EC) No. 258/97 on Novel Foods and Novel Food Ingredients. The governments of Austria, Luxembourg, Italy and France have responded by a moratorium and banned further imports of genetically modified maize and other crops unless it can be shown that health and environmental concerns have been adequately considered. Concern has also been expressed that users of genetically modified products need to be fully aware of the methods by which these products have been produced so that they can make informed choices. These same concerns are routinely expressed by a number of Member States in the course of the decision-making procedures for authorisation of genetically modified organisms under Directive 90/220/EEC.

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Biotechnology and Health Care: Consumer-Related Aspects

Dimitris Kyriakou and Duncan Gilson

Issue: Biotechnology, in its many guises, looks set to bring about something of a revolution in health-related products over the coming years. Genomics, genetic engineering and combinatorial chemistry, together will make more products, better matched to patients and diseases, come onto the market faster.

Relevance: Biotechnology has the potential to produce wide-reaching social and economic impacts. The accelerated rate of development of new and better tests, treatments and vaccines is likely to place a strain on health-care insurers and providers, as end-users press for access to a wider range of products. Matching drugs to patients will make genetic testing much more commonplace, and the issues of privacy and avoiding misuse of this information will need to be handled appropriately. Finally, we are likely to see not just products that save lives, but products that improve the quality of life, inevitably raising the issue of who pays and how.

Introduction

The ever increasing range of potential applications opening up to biotechnology (novel foods, smart materials, bioremediation, clean fuels, waste-water treatment, etc.) suggest it is likely to pervade many aspects of life in the future. The use of genetically modified organisms (GMOs) in foodstuffs is very much in the public eye at present and consumers, in Europe at least, are clearly divided over their benefits. The impact of food on health has become deeply ingrained in the contemporary consciousness, and having been taught that natural is best it will perhaps be hard for consumers to accept novelty in the immediate future. Nevertheless, 'functional foods' (or

nutraceuticals) (see *The IPTS Report 20*) or other foods with special nutritional properties resulting from biotechnology could prove attractive despite these qualms. This is particularly if they offer the possibility of reconciling contradictory desires, for example low calorie versions of otherwise fattening foods or cow's milk 'humanized' to make it better suited for infants. If, as some commentators say, there is little or no market pull for genetically modified foods outside of these niches, the pharmaceuticals business is at the other end of the spectrum, characterized by often extreme market pull for products which not only do not exist, but often seem to be little more than pipedreams. In this area at least some of the ethical and environmental concerns surrounding biotechnology tend to be offset by more pressing

worries about health, although concerns about the use of animals and possible human applications of cloning and gene modification are real.

The biotechnologist's toolkit

Biotechnology is the term applied to a range of new techniques involving the manipulation of biological material, particularly through the use of recombinant DNA, cell fusion and other new bioprocessing techniques. Among these technologies recombinant DNA (rDNA) technology, or 'gene splicing' as it is sometimes known, dates back to the 1970s. This basically involves manipulating DNA in cell-free systems (i.e. outside of a cell or organism) and then reintroducing it into the organism thereby transferring the new genetic information. Early examples of uses of this technology included the commercial production of human insulin in 1982 and transgenic, antibiotic resistant tobacco in 1983. Since then new applications have abounded, the only limitations apparently being the imagination, concerns about the rights of animals bred or genetically modified to develop certain diseases, and fears about the consequences of unleashing modified organisms on the environment.

Apart from the efforts of agro-chemicals companies and research laboratories to produce new supercrops using rDNA technology, the highest profile use of these techniques is probably the human genome project. The HGP is the continuation of other, less ambitious, gene mapping and sequencing projects (see Beese, *The IPTS Report* Issue 00) which have studied a range of organisms including bacteria, fruit flies and mice. The huge investment of effort is, predictably enough, bringing about advances in the techniques used, bringing down costs per base pair and accelerating the rate at which the work is completed. The most immediate outcome,

namely the ability to track the genetic origins of an increasing number of disorders and diseases, is a cause for concern in some sectors as no treatment is often available. However, the quantum leap in our understanding the underlying mechanisms operating in the human organism will undoubtedly lead to a wide range of new preventive and curative treatments.

The detailed genome map will enable comparison with existing animal genomes (mouse, fruitfly, etc.). This will speed up the identification of what is specifically human about the genome, bearing in mind that a large part of genetic information is common to all living creatures. This overlap naturally increases when the organisms are more closely related, but humans share large amounts of genetic material with organisms that appear to be very different from us. It would seem that once evolution found a way of performing some basic function it didn't bother to look for another. After the HGP the investigation into other genomes will no doubt continue. Detailed maps of an increasing range of organisms will make it easier to determine what models are appropriate for a given system as an objective measure of similarity with humans will be available. Using yeast, for example, for testing during the initial stages of drug development has huge benefits in cost and rapidity over using higher organisms, provided it is known that the mechanisms under investigation are the same.

A further development in the field comes from combinatorial chemistry, a technique which simultaneously creates a large array of peptides (short stretches of protein that are active in numerous cell functions), thus potentially speeding up the search for new active ingredients. Starting with an active lead molecule, this enables a single chemist to make thousands of different variations on the original molecule in a short time. Then these new modified compounds can be

Biotechnology's ability to offer hope of new treatments is likely to protect it in the case of pharmaceutical applications from much of the concern that is being expressed regarding biotechnology in the food industry

Genetic manipulation began to find commercially viable applications in the 1980s

The genome map of a human being will open up the way to greater understanding of a wide variety of mechanisms involved in both health and sickness

Techniques such as combinatorial chemistry shorten times needed to identify active ingredients, thus bringing drugs to the trial stage sooner

Many big players are positioning themselves so as to be able to take on the huge investments anticipated in drug development once as the results of genome research become available

Apart from the possibility of treatments for headline catching diseases, many of the degenerative disorders typical of old age may be brought more effective relief, which is particularly significant in the context of an ageing population

tested to see if activity has been improved. The challenges with this technology are in purifying and identifying the single modified compound that gives the enhanced activity. However, these problems are currently being solved by a number of different methods.

Testing ingredients at present still retains a large element of trial and error, but as knowledge of the underlying mechanisms improves and computer models become more accurate at predicting effects, the time to market, or at least time to trial, for new pharmaceuticals is likely to be shortened. Modern drug hunting means finding a chemical that blocks a specific protein, so the first step is to locate the target protein responsible for the disease. Then you need to test through thousands of chemicals to find the one that turns the protein off. If the protein is needed for a virus to invade a cell, or for a cancer cell to multiply, then the chemical is a potential new drug.

The biopharmaceuticals industry: large and small

The biotechnology and pharmaceuticals industries are clearly expecting major changes ahead. In the post-Human Genome Project era investments will be huge, but companies know that the race will be on to find drugs and get them patented and on the market before their competitors. Preserving the status quo will not be an option, thus to prepare themselves companies are consolidating as never before, and so presenting authorities with the dilemma regarding how to balance their distaste for quasi-monopolistic situations with the needs of the industry to spread the risk of the large investments needed if the possible rewards are to be reaped.

The complex science involved makes the issues confusing and potentially frightening for non-specialists. Information and open debate are

undoubtedly more likely to allay public fears in the longer term than paternalistic recourse to secrecy. Indeed some of the players in the sector seem also to think this is the best approach (for example, by setting up websites where views both for and against biotechnology can be discussed).

Current Health Needs and Issues

At the beginning of the century infectious disease was the leading cause of death in Europe and the US, accounting for 37% of mortalities. This figure had dropped dramatically to just 1.5% in 1993 (OECD, 1998). The result is that today, three out of every four deaths in the developed world are due to non-communicable diseases. Diseases of the circulatory system – heart attacks and strokes – are the largest single cause of death in developed countries accounting for about 46.7 per cent of total deaths, while malignant neoplasms account for 21.6 per cent of deaths (OECD, 1998). Communicable diseases remain a threat, however, and diseases such as AIDS and multi-resistant tuberculosis urgently need vaccines and/or treatments that are within the reach of the world's poorer countries.

However, for the developed world in particular the increasing number of elderly people is, or will become, a major concern. According to the WHO, the world's population has been growing at an annual rate of 1.7 per cent during the 1990-95 period, but the population over 65 years is increasing at a much faster pace, by some 2.7 per cent annually. The implications of this growth will be to bring to the fore ailments which particularly affect the elderly, especially those chronic degenerative diseases which still lack an effective cure, such as arthritis, dementia, cancer, etc. As ever the question of improving health in old age is one of both quality of life and reducing dependence on health and social services. Appropriate tools to assess the

outcomes of potential treatments from this perspective are urgently required in view of confident predictions that biotechnology will be offering new diagnostics and genetic therapies in the near future.

Health in the 21st Century

The knowledge and techniques offered by biotechnology amount to the beginnings of new approach to drug discovery (and increasingly substituting discovery by design), production and delivery. These advances offer hope of treatment for diseases which have resisted traditional techniques. The influence of genes has been identified in various forms of heart disease, breast and colon cancer, diabetes and arthritis, and the genes for cystic fibrosis, Duchenne muscular dystrophy, neurofibromatosis and fragile X-linked mental retardation have been isolated. And these are just a few of the more than 4000 gene-related illnesses (OECD, 1998). As research in this field progresses the genes underlying other diseases will be uncovered and new insight will be gained into the processes involved in the commoner life-threatening ailments.

The ageing population in the world's wealthier countries is likely to create a situation in which an increasing number of people require treatments for chronic, degenerative diseases (many of which are currently treated only symptomatically as they lack therapeutic solutions), whilst the size of the working population supporting the health care system is shrinking. Biotechnology may well provide therapies which strike at the causes of these ailments, but these are not likely to be cheap. Moreover, as the population ages, so do voters. It may prove politically impossible to keep a lid on expenditure unless long term planning issues are tackled in the way they are being looked at for the case of pension provisions.

Apart from its role in tackling scourges such as cancer through the development of innovative new treatments, the new scenario in the biomedical industry will probably bring about more subtle changes. More rapid development times and more sophisticated ways of designing drugs inevitably mean that there will be a greater variety of pharmaceuticals available. This range will include more treatments for previously untreated diseases, and also more specific treatments for certain common diseases. By combining genetic testing with the prescribing of certain types of medication it may prove possible to take some of the guesswork out of the process and match specific treatments to specific groups of patients. But by making offering a bewildering range of possible treatments available for the same disorder, it may place greater burdens on regulatory authorities, doctors and finally consumers attempting to sort out the wheat from the chaff.

Genomics research: opportunities and challenges

Apart from its likely longer-term impact on treatment and prevention, research into the human genome is already giving rise to the possibility of testing for a range of genetic predispositions to disease. The principle of screening the unborn for genetic damage is not new. A test to detect the chromosomal damage typical of Down's syndrome has been available for some time. In the future tests which look for more subtle variations in a DNA will become available to detect more of the congenital abnormalities which are still a major cause of death during the first year of life (25-60 liveborn infants per 1000 are estimated to have congenital abnormalities, OECD 1998).

Genomics also offers the possibility of screening adults for disorders which they may be predisposed towards later in life. This will be a

The genes involved in some of the 4000 or more gene-related illnesses have already been identified

Genetic testing promises screening for an increasing range of disorders, but will need to be monitored carefully to avoid inappropriate use or threatening privacy

The coming decades are likely to see unprecedented growth in the number of new pharmaceuticals available. Some will be lifesavers, others may improve the quality of life for sufferers of chronic conditions or extend life just that little bit further

valuable technique if it is coupled with adequate follow-up and preventive programmes, as in the case of breast cancer tests for example, but is likely to cause unnecessary distress if there is in fact no treatment available, such as in the case of tests for Huntington's Chorea. Discussion of the issues surrounding testing have been postponed whilst the spread of the technology has been kept in check by its price, but already cheap devices are appearing on the market. The rights and responsibilities of insurers need to be defined in this area if overall public interests are to be balanced with actuarial logic (for example, in the 80's insurers in some countries effectively discouraged voluntary HIV-testing by obliging policy applicants to disclose whether they had been tested). The question of who is allowed to be tested for what will also need to be considered. Unscrupulous genetic testers may emerge offering gene tests for predispositions to health problems related to tobacco or dietary cholesterol. Consumers who decide not to modify unhealthy behaviours because as a result of these tests they consider themselves to be 'immune' may place a strain on health-care providers. In any event, genetic testing will produce a new series of medical data, and it must be ensured that the same levels of privacy are given as for other medical data. The need for control in this respect is aggravated by the relative ease with which biological samples may be obtained. In the longer term it may prove necessary to establish legislation or codes of practice analogous to data protection regulations governing human biological specimens. All in all, the way this field shapes up is clearly a matter of speculation, and it is precisely this uncertainty over the potential outcomes that makes a 'watch-dog' approach seem prudent.

Life-style drugs and life-saving drugs

There is never room for complacency about the power of medical science to combat disease,


whether drawing upon biotechnology's armoury or not. AIDS and BSE-related encephalitis serve as a reminder of the complex and refractory nature of some illnesses. Multi-resistant tuberculosis demonstrates that enemies that once seemed to have been conquered can indeed fight back. Nevertheless, medical science has made developments which have resulted in greater longevity, and against backdrop of increasing expectations, this can add up to unexpected demands on health-care systems designed in an epoch when simply saving lives was difficult enough.

Recent experience shows that in matters concerning health demand expands to match the treatments available, whereas of course budgets do not. The coming decades are likely to see unprecedented growth in the number of new pharmaceuticals available. Some will be lifesavers, others may improve the quality of life for sufferers of chronic conditions or extend life just that little bit further. Yet others may treat conditions, such as baldness or limited stature in children, which may not even be universally classified as disorders.

Clearly, as drugs become available so people will demand them. Moreover, recent history suggests they will demand them with ever increasing militancy. Systems in which the authorities issue lists of what is and is not covered by the health-care system are likely to be overloaded by sheer numbers of products to approve (or 'disapprove'), and they risk turning themselves into the object of constant attack from one pressure group or another demanding treatment for 'its' problem. Coherent frameworks are likely to be needed to avoid conflicts arising or to channel them when they do, in such a way that all stake holders have the opportunity to express their views in a structured way.

Society is sensitive about substances which alter the functioning of the human organism. At one end of the spectrum this is reflected in legislation which prohibits the use, or at least possession, of certain substances (notably psychotropic drugs), but further down the scale it is also reflected in health-care policies which set limits on what ailments they are willing to treat. The biomedical revolution will not alter the fundamentals of this situation, just as information technology did not invent information.

The possibility of expensive treatments emerging for life-threatening illnesses imposing

burdens on health care providers may well force a rethink of their approach to 'minor' ailments. At the same time an increasing number of treatments, including some for conditions which may not universally be considered appropriate matters for medical practitioners to deal with may impose the need for a more logical approach to what is allowable. However, those electing the easy option of allowing nothing, or as little as possible, will have to confront ever more militant 'consumers' of these treatments and the problem of how to control cross border 'trade' and shady clinics setting up on the territory of more liberal neighbours. 

Keywords

biotechnology, pharmaceuticals, health care

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The Supply of Information to the Consumer: When More is Actually Less

Ioannis Maghiros, *IPTS*

Issue: Consumers, at the centre of an efficient electronic market, are increasingly using novel Internet-based technologies in order to identify high quality products, better services and prices. Sellers, also making use of the latest technological advances, present their merchandise on the Internet profiting from online-collected detailed consumer-specific information.

Relevance: Too much information to scan through may ironically make selecting more difficult. Targeted advertising raises questions of privacy rights and moral concern about the use of information. Measures ought to be studied that would educate the consumer early on, as to how to combat Information Overload, as well as keep an eye on key actors and the way in which they might exploit their dominant market position.

Introduction

Internet text indexes and search engines have been a key factor in the growth in popularity of the World Wide Web, but this growth has meant that the amount of information these services provide is often overwhelming for users

The proliferation of information available on the Internet as a result of the increase in the number of online users and the number of interconnected nodes has triggered the need to develop indexed information and new software tools for searching distributed indexes. Self-proclaimed gatekeepers have developed indexes and search engines which have greatly boosted WWW usage. Spiders and Crawlers, i.e. software robots that travel the Web continuously index all the text they find (current estimates calculate some 70 million on-line pages) and general-purpose software interfaces help end-users identify specific information sources by a variety of means (e.g. subject directories, free-text search, advertising banners,

'intelligent agents', etc.). The result is the problem of being inundated with information, somewhat like trying to quench your thirst with a fire hose. This, however, also signals a business opportunity for the developers of novel filtering techniques.

The gradual commercialization of the Internet places the online-user cum consumer at centre stage and empowers him/her by means of (mostly free) software tools allowing him/her to determine which products and services to view and purchase from among those available on the basis of their value for money. Sellers are also benefiting from the electronic marketplace through the creation and running of virtual shop fronts, which are easy to set-up and cheap to run. One approach to the problem of managing customer communication is to use 'intelligent'

data files called cookies¹ that store customer specific information. Consumer-goods companies use consumer identity attributes (eg. age, sex, online decisions) as well as purchasing information to provide tailored information to their target markets. In the light of the dominant revenue models in this emerging market, the variety of specialized tools that convey information enabling "best buys" to be selected and the impact that this flood of information will have on the consumer, this article seeks to draw attention to some of the policy challenges ahead.

Marketing Consumer Products and Services on the Internet

The ease of setting up shop on the Internet and the promise of attractive profits has enticed a whole host of players. These use various mechanisms for revenue raising, including advertising, pay-per-view and subscription. Of these, the **advertising** model involves other companies placing advertisements on Web sites, which are usually run by content providers for whom advertising is usually their main or only source of revenue. Once considered an inappropriate use of the Internet, Forrester Research, a consultancy firm, signals that expenditure on advertising on the Internet will increase 10-fold between now and the year 2003 (\$1300M, 1997 and \$15000M, 2003). However, this still represents less than 5 percent of total advertising expenditure worldwide. The advantage of the advertising model lies in the development of tools that allow companies to learn what the world's increasingly sophisticated and sceptical consumers are thinking and respond quicker than ever before, thus forging stronger relationships with consumers. Most on-line advertising today takes the form of banner ads, the wide, shallow rectangles often seen at the top or bottom of Web pages, which if clicked with a mouse take the user to the advertiser's Web site.

But these banners are being largely dismissed as being too small and simply too ineffective. Novel advertising systems are currently being designed including transactional ads and rich-media ads².

Another model is that of offering services through **subscription**. This is attractive to content providers because it guarantees revenue. It is a 'push' technology model, similar to the broadcasting model governing today's media world. This system is more suited to information management professionals who need very high levels of information to perform effectively. It is primarily for this type of users that tools have been developed to enable filtering and automatic rejection of unsolicited information. Consumers requiring more customized and personalized services are less likely to support this model. A variant of this system enabling access by a broader set of consumers, is the **pay-per-use** model. The strong points of this model are on the one hand, the cost-effective customization of products according to individual preferences addressing individual consumers' needs and greater control over copyright, and on the other, payment of individual pieces of information on an ad hoc basis. Nevertheless its diffusion is dependent on the widespread adoption of a micro-payments infrastructure, and this is currently not available. **Hybrid** models incorporating any combination of the above are likely to become profitable in the near future – such as for example the try-before-you-buy model. Technology is strongly influencing the development of products, pricing models and strategies for the future.

Technological solutions to enhance consumers' knowledge

Companies spending millions on advertising on the Internet are investing in web-based technologies that enable direct personalized

For retailers the Internet offers low start-up and running costs for their virtual shop and unprecedented ability to profile and target their actual and potential customers

Advertising is becoming the dominant revenue source on the Internet, and part of its attraction for sellers is the feedback it gives on the reactions of the world's increasingly sophisticated and sceptical consumers

Portals, a recent evolution of gateways, and electronic agents, are being developed to enable Internet navigation by filtering information

Using meta-information is a more sophisticated approach to information retrieval and one which offers more possibilities for intelligent customization

marketing of products and services. Gateways are web sites which host search engine indexes. They enable pass-through access to an array of Web sites either through general-purpose free-text search mechanisms or by providing a hierarchical thesaurus of sites for a broad range of audiences, based on demographic, key-subject and geographic interests. Portals, a recent evolution of gateways, enable Internet navigation, accessing a broad range of content and services, and communication with others online. In general they offer some services for free so that they may then profit by identifying distinct user communities and suggesting suitable services for a fee.

Improved information sharing between buyers and sellers helps lower the cost of logistics and promotes rapid, just-in-time delivery and reduced inventory. Many systems have therefore been developed to enable this type of bilateral transactions aimed at lowering buyers' search costs and sellers' marketing overheads (e.g. PriceWatch, ComputerESP and Travelocity). Other systems addressing a variety of information needs, such as preferred lists of Web sites depending on user profiles³, software auction tools⁴ and automated price negotiators⁵ have also been developed commercially. While currently the emphasis is on tools tracking the best available price on offer, there is a growing preference for tools able to compare quality attributes, which is beneficial for the market at large (offering quality to buyers and less of a price war for sellers).

Obviously enough, retrieval procedures based on keyword indexes are not sufficient given the volume of content available. Research into systems that provide meta-information (information on information) is ensuring that these systems are elaborate enough to present diverse values and interests. Another important way in which sites may be customized is through

localization, where cultural and linguistic distinctions will lead to the emergence of regional content sites, especially in Europe, which will become dominant audience attractions. The search for, and retrieval of, public information is also pertinent in the drive towards a more empowered consumer. While European corporations have taken the lead in Web localization, successfully adapting products, brands, and prices to meet local market variations (in Europe, 80% of corporate sites are multilingual, with English the preferred second language) few U.S. companies address the needs of their international audience. Although localization is expensive, adding between 10% to 60% to a site's development costs, localized sites generate more traffic, longer visits, and greater customer satisfaction.

The impact on the consumer

Consumer-goods companies, technology companies, content providers, portals and Web-based intermediaries across the globe are rapidly trying to address the problem of communication with the consumer via the Web. But as technology makes it easier for companies to gather information on consumers these must also accept the responsibility that comes with that information.

Consumers are becoming more concerned about threats to their personal privacy as companies are increasingly able to process data related to personal details and purchasing habits. The current attitude to user-profile data collected is that it is too valuable to disregard but not likely to be used for the time being as no one really knows how to process it (although research on data mining techniques is on the increase). In general consumers are willing to share personal information if companies provide them with clear benefits (usually price discounts). The solution to

this perceived data-privacy problem therefore resides in controlling the flow of this information in a way that should in principle be both transparent to the consumer and traceable.

The mechanisms used differ between countries: European countries ensure the protection of electronic data through regulation, whereas the United States Government encourages agreements or codes of conduct between industry and consumer representatives. Directive 95/46/EC, the European directive to be implemented⁶ from 25 October 1998, provides for a high degree of protection within the European Union, for the treatment of data of a personal nature. It also comprises an external chapter submitting exchanges of private data with third countries to strict criteria, which has caused some concern to governments and economic players in some third countries. This difference in practices gives rise to the question of whether companies will be required to maintain two web sites to cater for consumers on different continents. It could well be that the WTO with its wide membership and binding dispute settlement procedures, may be an appropriate setting in which further progress on data protection could be made. The OECD⁷ could also play a major role in this context.

The World Wide Web Consortium (W3C), the international industry consortium which acts as a monitoring body for the Web⁸, has developed a mechanism to support consumer data protection. The Platform for Privacy Preferences Project (P3P) has been designed to promote privacy and trust on the Web by enabling service providers to disclose their information-processing practices, and enabling individuals to make informed decisions about the collection and use of personal information relating to them. Special P3P software agents installed on client machines transact on behalf of individuals and reach agreements with

other P3P software agents installed on service provider machines about the collection and use of personal information. Transactions are allowed to proceed when a match is found between web site practices regarding application of relevant laws and principles of data protection and privacy and user preferences. In addition, there are various other suggestions, concerning voluntary regulation of data collection and use, being considered in the debate on both sides of the Atlantic.

Beyond the risk of individual loss of privacy, there is also the risk of tampering with the information provided. Since gateways provide the tools that enable users to filter unwanted information, there is concern over their control of the electronic directories and therefore content. Whilst the risks of this happening are minimal, there is however a race for more visible and better-positioned data on a portal type of web-site. The money to be made out of having the blessing of the gatekeeper seems to be tempting enough for Netscape, the browser-software company, to prefer to compete in this market as a portal. Finally, the collection of personal data from children, a growing category of online users, should be carefully addressed⁹.

Challenges

The proliferation of information on the electronic networks, both public and private, has given consumers the choice of a wide variety of products and services and sellers an even wider array of marketing tools. Thus a situation which was apparently beneficial for all concerned has given rise to an information overload, i.e. a situation in which users receive too much unwanted information, as with more users on-line there is now so much more content available and so many more ways to access content. Challenges

Some users may not object to their personal details and purchasing habits being recorded by Internet retailers if this means benefits for them, such as user-profile-matching services or discounts for loyal customers

Different national approaches to the issue of privacy worldwide run counter to the globalizing tendency of the Web and global forums could be an appropriate setting for debate on this issue

The challenge now is to maintain the beneficial elements of knowledge generation while at the same time decreasing the plethora of unsolicited information

Among other things, solutions will focus on ever more intelligent filtering at the user end and more intelligently structured data – including meta-information – at the provider end

European users need to be equipped with the necessary understanding of how to build up criteria with which to judge from a European, diversity-exploiting perspective

arise out of the desire to maintain the beneficial elements of knowledge generation while at the same time decreasing the plethora of unsolicited information.

- **Automatic Filtering Systems:** a solution already developed is to use tools that exclude 'non-information' either by aiming at defining the subject searches more precisely or by limiting search scope more objectively. In this case more research is needed in the fields of Information Retrieval, Artificial Intelligence and Relevance Theory. Private individuals (unlike professionals) are more prone to constantly changing their online behaviour and so require a new generation of intelligent agents to combat information overload.
- **Contextual information:** another solution, recently applied to Web propagated data, is to base consumer trust on mediated information sources thus highlighting the weight of contextual information or meta-information; initially denoting "information about information" it is now interpreted as "machine understandable information, about information on the web". Meta-information will facilitate searching, by enabling authors to describe their documents in ways that search engines, browsers and Web crawlers can understand their content. In this case more research is required into computer-friendly knowledge representation languages, sector-specific vocabularies and filter definitions.
- **Data-privacy Protection Protocols:** Novel advertising techniques and better-focused consumer advice (distinguished by more tools to enable the identification of the right product at the right price) are a welcome evolution of the market for consumer products. In spite of that, the lack of knowledge and control over the use of the personal information that these disclose, denotes the need for specific data protection regulation. Consumers should be fully aware of Web site privacy policies for the

market to function well beyond initiatives like P3P by W3C. In this case and on top of agreeing on an internationally acceptable regulatory framework, some kind of controlled licensing/permitting¹⁰ on service providers should be exercised so that implementation of stated practices is supervised for the benefit of the consumer. In addition, by regulating liabilities of the intermediaries, concerns over the lack of means of controlling the integrity of the broker and/or the gatekeeper may be abated.

- **Educating the Consumer:** Finally, the proliferation of information sources is likely to bring about an increasing number of cases where conflicting information will be obscuring the decision making process. Individuals seem to require more information processing skills and the consciousness of personal responsibility over decisions to be made. In addition, consumers should be educated to protect themselves from activities that make poor use of their time and intelligence. Thus it will be necessary to acquaint the consumer early enough, with the necessary understanding of how to build up his/her own set of criteria with which to judge – a European multi-lingual, multi-choice system. The overall objective is to enhance a consumer's critical ability to make more 'intelligent' choices and thus help in the functioning of a primarily information market.

Conclusions

As technology makes marketing to individuals possible and the European e-commerce market increases its turnover, it seems likely that there will be a transition from an Internet revenue model based on access fees to one based on transaction and advertising revenues. Moreover, individuals are empowered by such technology integration to identify quickly and simply what is

relevant, thus giving birth to an "intelligent consumer". Choice-enabled consumers through new devices, tools, and services will continually be pressing for better deals, making it more difficult for businesses to create long lasting relations with this type of consumers.

Commercial organizations will attempt to forge profitable relationships with customers and they are likely to use extracted customer-specific information for this purpose. Hence the growing battle over the control of portals that are able to build comprehensive user-profiles by offering

services for free in order to raise and maintain consumer confidence. Consumers will also have to be educated to cultivate their own selection system and not adopt ready-made recipes. In this case consumers and their associations will treat intermediaries and service providers that do not readily adopt a clear data processing policy with increasing suspicion. The result may be a radical rethinking of how products are marketed sold and distributed on the Internet. At the same time, more and better technology will enable consumers to search and select avoiding being overloaded with unwanted information. ●

Keywords

information Society challenges, e-commerce, Internet advertising, consumer data privacy protection, information overload, European value system

Notes

- 1- Whenever a user accesses a Web page for the first time, the server assigns a specific identification number (cookie) to the user and transmits a data file that resides on the user's PC and gets updated whenever the user visits the Web page again with basic data attributes revealing details about the customer's environment.
- 2- Transactional ads are designed to create a two-way flow of information, enabling interaction (eg. VTAG from First Virtual); rich media ads include audio-enhanced banners and streaming audio-video advertising.
- 3- The Direct Hit Popularity Engine, is a search engine that analyses Internet selections made by a user, during his online time and then by comparing with known patterns from other users, presents a list of preferred sites for the specific user.
- 4- Onsale.com auctions last minute unsold airline tickets.
- 5- Tête-à-Tête, developed by MIT, negotiates purchase on behalf of buyers and sellers.
- 6- The implementation of this Directive by Member States has been delayed, in order to allow more time for negotiations between the Commission and the U.S. administration to reach an agreement.
- 7- The latest OECD Conference, in Ottawa, Ontario, 7-10 October 1998, is another likely forum for promoting consumer protection issues, due to the simultaneous presence of world government authorities and representatives of both consumers and the business world.
- 8- The W3C was founded in October 1994 to lead the World Wide Web to its full potential and is jointly hosted by the Massachusetts Institute of Technology Laboratory for Computer Science [MIT/LCS] in the United States; the Institut National de Recherche en Informatique et en Automatique [INRIA] in Europe; and the Keio University Shonan Fujisawa Campus in Japan.

About the author

Ioannis Maghiros holds a Master's Degree in Information Science from the University of Birmingham, UK, having previously studied Physics at the University of Patras, Greece. He worked for IBM in Greece before joining the IPTS-JRC in 1990, where he works as a scientific officer and is currently responsible for the production of The IPTS Report and the development of the IPTS Web site. His main research interests include the impact of ICT's on the economy and society and Web-based workgroup tools.

9- In a report to the U.S. Congress on Privacy Online it is stated that of all Web sites that appeal to children, 90% of them collect personal information and about half of them do not disclose what they do with it; parental consent for children under 13 years of age could be a solution to this problem.

10- eTRUST is a seal service, a "trustmark" jointly developed by the Electronic Frontier Foundation (EFF), the online free-speech advocates and CommerceNet the not-for-profit e-commerce organization.

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Related URL's: VADz is a form of Java applet developed by the Transactional Media Unit at First Virtual Holdings <http://www.firstvirtual.com/services/vtag.html/>; Altavista Search Service <http://altavista.digital.com/>; The Price Watch web-site <http://www.pricewatch.com/>; ComputerESP is the engine of Cnet's shopper online shop, <http://www.shopper.com/>; The BizRate Guide maintains a merchant's reputation database from information provided by users of their systems, <http://www.bizrate.com/display.pl/>; Priceline is a buying service that lets you name your price; the buyer specifies product requirements and a price he/she is willing to pay and collects sellers' offers <http://www.priceline.com/>; The Internet Auction Web site <http://www.onsale.com/>; The Internet online travel agency Travelocity allows customers to set their preferred price, <http://www.travelocity.com/>

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A B O U T T H E I P T S

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1. Technology Watch. This activity aims to alert European decision-makers to the social, economic and political consequences of major technological issues and trends. This is achieved through the European Science and Technology Observatory (ESTO), a European-wide network of nationally based organisations. The IPTS is the central node of ESTO, co-ordinating technology watch 'joint ventures' with the aim of better understanding technological change.

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