

**From Genetically Modified Organisms To Synthetic Biology:
Legislation in the European Union, in Six Member Countries
and in Switzerland**

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The views and opinions expressed are those of the author of the paper.

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Introduction

This report is based on the assumption that in Europe and in its member countries—with the exception perhaps of Switzerland—“synthetic genomics” as a distinct policy domain does not yet exist. This conclusion is based on considerable empirical evidence. Since I was approached last October (2005) by the project leaders I have systematically been monitoring the use of this term in the news media around the (English speaking) world. I have done so in two ways: with the help of several Google search robots and by scanning various Lexis-Nexis news databases using the term “synthetic genomics” and its translation in German, Italian French, Spanish and Dutch.

The search has produced very modest results. To date, there has been very few instances of news reporting focused on synthetic genomics. One of them was the founding by Dr. Craig Venter of Synthetic Genomics. Another one has been the launch of the project this review paper has been prepared for. And the third one was the appointment of Dr. Ari Patrinos to President of Synthetic Genomics. In addition, there has been sporadic report on the discipline itself, but rarely in connection with possible novel risks. With regard to Europe, no news stories have been found focusing on synthetic genomics per se or on possible new dangers stemming from its development.

The results emerging from the media analysis are entirely consistent with the EU priorities in the area of public health and consumer protection. The EU Directorate General on Consumer Protection and Safety over the years has established numerous scientific committees and advisory boards. Each of these committees is focused on a specific policy domain and is responsible for advising the European Commission on

matters pertaining to its area of expertise. Based on the available information, it appears that none of the currently chartered scientific and regulatory committees has included synthetic genomics in its policy agenda. In 2003 the Scientific Committee on Emerging and Newly Identified Health Risks prepared a report for the Commission titled “Priorities in the EU for Risk Assessment in the Non-Food Area”. The report examines a wide variety of possible future threats to the health of European citizens and to the natural environment. The document runs 76 pages but contains no reference to either synthetic genomics or synthetic biology.

It would have been highly interesting to discuss with the Committee members whether the subject of synthetic genomics has been identified as a possible future area of concern, and if so the reasons for not including it in their report. Unfortunately, several attempts to get in touch with this committee and its members have produced no tangible results. In 2004 the Commission enacted very stringent procedural rules designed to prevent or mitigate attempts at influencing the Committee members, to ensure transparency and more generally good governance. These rules have prevented me from obtaining any feedback, formal or informal, for attribution or on background, from the Committee secretariat or the Committee members. Among other things, these rules do not allow the Committee to provide any information to individual citizens, i.e. individuals with no recognizable institutional affiliation. These limitations notwithstanding it is reasonable to assume that “synthetic genomics” currently is not on the agenda of European policy-makers. For this reason this report does not attempt to identify legislative or regulatory measures taken by the EU or its member countries and targeted at synthetic genomics proper, as these measures simply have not been taken.

A more interesting question is whether “synthetic biology,” as opposed to synthetic genomics, has attracted the attention of European policy makers. Unlike synthetic genomics, synthetic biology is being regarded by the Research Directorate-General as a scientific discipline in its own right, albeit a very young one. Synthetic biology was not included in the 6th Framework Program (FP), and it is unclear whether it will be included in the 7th FP. However, the EU has begun funding synthetic biology as part of its NEST (New and Emerging Science and Technology) activities. Synthetic biology, whose

research agenda and priorities have been described in a recently published expert report, appears to share many of the goals synthetic genomics purports to pursue. For example, both disciplines envision adopting a rigorous engineering approach to the design of organisms as it is common in mechanical and electrical engineering. That these two fields are quite similar is not entirely surprising, considering that two of the authors of the EU experts report are based in the United States, with strong ties to the scientific leaders in synthetic genomics. For this reason, in this report I will be focusing on the synthetic biology rather than on synthetic genomics.

Whether EU policymakers regard synthetic biology as a scientific development distinct from genetic engineering, and whether this scientific discipline is likely to create genuine new challenges is a question that at this time cannot be answered with any degree of confidence. As mentioned earlier, EU officials have not been willing to provide any insight. On the other end, anecdotal evidence suggests that the scientists—when it comes to assessing possible risks and dangers associated with synthetic biology—do not believe that this scientific development is likely to create any fundamental new challenge. In this view when it comes to the risks to human health, safety and the natural environment synthetic biology is no different than genetic engineering as practiced over the last 25 years. Accordingly, these scientists have expressed the view that the rules and regulations currently in place and governing research activities in contained environments, as well as the regulations designed to protect the health and safety of the personnel working in these environments and the measure taken to minimize the risks associated with the release in the natural environment of genetically modified organisms, with few exceptions, are more than adequate for the task at hand.

Whether this conclusion is shared by a majority of the scientists operating in this field remains to be seen. It appears that regulators may differ somewhat in their assessment of the risks posed by this new scientific development. Also largely unclear at this point is whether malicious intent is being considered by either policymakers or scientists as a serious threat.

Based on the working hypothesis that synthetic biology, for a while at least, is not likely to pose many new threats to health, safety and the natural environment in the remainder of this paper I have compiled the laws and regulations pertaining to the contained use of genetically manipulated (or modified) organisms (GMOs), to the safety of the personnel involved in contained facilities and their surroundings and concerning the release of GMOs in the natural environment. The review includes EU norms as well as laws and regulations adopted in Germany, Britain, France, Italy, Austria, Belgium and Switzerland. The selection of these countries was motivated by both conceptual and practical considerations. I have included European leaders in science and engineering such as Germany and the United Kingdom, but also smaller countries such as Belgium, Austria and Switzerland. Switzerland, while formally not a member of the European Union, is actively involved in synthetic biology and entertains close ties with the European Union in all policy areas, including science policy.

Austria

Statutory Framework

- **BUNDESGESETZ, mit dem Arbeiten mit gentechnisch veränderten Organismen, das Freisetzen und Inverkehrbringen von gentechnisch veränderten Organismen** und die Anwendung von Genanalyse und Gentherapie am Menschen geregelt und das Produkthaftungsgesetz (Gentechnikgesetz (GTG) – BGBl. I Nr. 510, July 7, 1994)
- **BUNDESGESETZ über Sicherheit und Gesundheitsschutz bei der Arbeit** (ArbeitnehmerInnenschutzgesetz (ASchG) – BGBl. Nr. 450, June 17, 1994)

Deliberate Release of GMOs in the Environment

- **VERORDNUNG** der Bundesministerin für Gesundheit und Frauen über Inhalt, Umfang und Form von Anträgen auf Genehmigung einer Freisetzung oder des Inverkehrbringens von gentechnisch veränderten Organismen, die Sicherheitsbewertung und den Überwachungsplan –(Freisetzungsverordnung – BGBl. II Nr. 260, August 24, 1997)

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Contained Use of Pathogenic and/or Genetically Modified Organisms

- **VERORDNUNG** des Bundesministers für soziale Sicherheit und Generationen über die Sicherheit bei Arbeiten mit gentechnisch veränderten Organismen in

geschlossenen Systemen (Systemverordnung – BGBl. II Nr. 431, November 29, 2002)

- **VERORDNUNG** der Bundesministerin für Gesundheit und Konsumentenschutz über das Anhörungsverfahren gemäß dem Gentechnikgesetz (Anhörungsverordnung – BGBl. II Nr. 61, February 28, 1997)

Protection of Workers Exposed to Biological Agents at Work

- **VERORDNUNG** der Bundesministerin für Arbeit, Gesundheit und Soziales über den Schutz der Arbeitnehmer/innen gegen Gefährdung durch biologische Arbeitsstoffe (Verordnung biologische Arbeitsstoffe (VbA) – BGBl. II Nr. 237, July 23, 1998).

Regulatory Authority

- Bundesministerium für Arbeit Gesundheit und Frauen: Health related rules and regulations
- Bundesministerium für Bildung Wissenschaft und Kultur, Bereich Gentechnik und Tierversuchswesen: Contained use of GMOs
- Bundesministerium für sozial Sicherheit, Generationen und Konsumentenschutz: Contained use of GMOs
- Bundesministerium für Gesundheit und Frauen: deliberate release of GMOs
- Bundesminister für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft: commercial distribution of GMOs

Entry Points

- Dr. Michel Haas
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- Bundesminister für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft
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Belgium

Legal Framework

Belgium, unlike other European countries, has not enacted comprehensive legislation pertaining to the contained use and intentional release of GMOs in the environment. Rather, it has adopted and implemented most relevant European directives.

While in the case of the deliberate release of GMOs Belgium has passed regulations at the federal level, it has delegated to the regions the task of implementing European legislation regarding contained use of GMOs. However, the evaluation of research proposals involving the genetically modified organisms is conducted by a national scientific committee. This common advisory system is founded by a Cooperation Agreement concerning Biosafety.

Deliberate Release of GMOs in the Environment

- **ARRÊTÉ ROYAL** du 21 février 2005 réglementant la dissémination volontaire dans l'environnement ainsi que la mise sur le marché d'organismes génétiquement modifiés ou de produits en contenant. (Moniteur Belge, February 24, 2005, p. 7129) : This Decree implements and enforces Directive 2001/18/EC.
- **LAW of February 22, 1998 (amending the law of July 20, 1991), especially articles 222 and 226.**
- **LAW of July 20, 1991, especially article 132:** provisions concerning the deliberate release in the environment of genetically modified organisms.

Contained Use of Pathogenic and/or Genetically Modified Organisms

- The European legislation has been transposed at the regional level as a part of the Regional Environmental laws for classified installations.
- These regulations implement European Directive 98/81/EC revising Directive 90/219/EEC, and related Decisions 2000/608/EC and 2001/204/EC.

Protection of Workers Exposed to Biological Agents at Work

- **ARRÊTÉ ROYAL** modifiant l'arrêté royal du 4 août 1996 concernant la protection des travailleurs contre les risques liés à l'exposition à des agents biologiques au travail (Moniteur Belge, p. 37917, October 7, 1999)
 - This royal decree implements European Directives 90/679/EEC and Amendments 93/88/EEC, 95/30/CE, 97/59/CE and 97/65/CE.

The Cooperation Agreement

- The “Cooperation Agreement between the Federal State and the Regions on the Administrative and Scientific Co-ordination Concerning Biosafety” establishes a single scientific advisory system common to the Federal and Regional authorities scientific aspects related to the uses of genetically modified organisms (GMOs) and pathogens are assessed in a coordinated way.
- The common scientific evaluation system is composed of the Biosafety Advisory Council (BAC) and the Service of Biosafety and Biotechnology (SBB).

Advisory Boards

- **Biosafety Advisory Council**

- The BAC advises the competent authorities on the safety of any activities using GMOs and pathogens, including genetic and ecological aspects related to biodiversity.
- The Council can be consulted by the Regions or the SBB for the contained use activities (laboratories, greenhouses, animal husbandries, production plants). It must be consulted for the deliberate release of GMOs in the environment and the placing on the market of all GMOs and GMO-based products.
- The Council consists of representatives of the Regional and Federal authorities. It is assisted by experts in its scientific work. The secretariat of the Council is ensured by the SBB.

- **Service of Biosafety and Biotechnology**

- The Service of Biosafety and Biotechnology (SBB) is composed of an administrative secretariat, a multidisciplinary group of scientists and a laboratory for biosafety research and expertise.

- **Regulatory authority**

- Service public fédéral (SPF) Santé publique, Sécurité de la Chaîne alimentaire et Environnement (Federal Public Service (FPS) Health, Food Chain Security and Environment): Deliberate release into the environment of GMOs.
- The regulatory authority for the contained use of GMOs is delegated to the three federal regions (the Flemish, Walloon and Brussels-Capital region).
- Ministère fédéral de l'Emploi et du Travail, Administration de l'hygiène et de la médecine du travail (Federal Ministry for Employment, Work, Hygiene and employment medicine Administration): responsible for Worker safety.

Entry Points

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European Union

Deliberate Release into the Environment of Genetically Modified Organisms

- **COMMISSION DECISION 2004/204/EC** of 23 February 2004 laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council (Official Journal L 65, 3.3.2004, p. 20)
- **COMMISSION REGULATION (EC) No 65/2004** of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5)
- **COUNCIL DECISION 2002/813/EC** of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market (OJ L 280, 18.10.2002, p. 62)

- **COUNCIL DECISION 2002/812/EC** of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products (OJ L 280, 18.10.2002, p. 37)
- **COUNCIL DECISION 2002/811/EC** of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 280, 18.10.2002, p. 27)
- **COMMISSION DECISION 2002/623/EC** of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 200, 30.7.2002, p. 22)
- **DIRECTIVE 2001/18/EC** of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)
 - Directive 90/220 CEE du 23 avril 1990 relative à la dissémination volontaire dans l'environnement d'Organismes Génétiquement Modifiés (OGM).

Contained Use of Pathogenic and/or Genetically Modified Organisms

- **COMMISSION DECISION 005/174/EC** of 28 February 2005 establishing guidance notes supplementing part B of Annex II to Council Directive 90/219/EEC on the contained use of genetically modified microorganisms (notified under document number C(2005) 413) (Text with EEA relevance). Official Journal L 059, 05/03/2005 p. 20 – 25.
- **COUNCIL DECISION 2001/204/EC** of 8 March 2001 supplementing Directive 90/219/EEC as regards the criteria for establishing the safety, for human health and the environment, of types of genetically modified microorganisms (Text with EEA relevance) Official Journal L 073, 15/03/2001 p. 32 – 34.
- **COMMISSION DECISION 2000/608/EC** of 27 September 2000 concerning the guidance notes for risk assessment outlined in Annex III of Directive 90/219/EEC on the contained use of genetically modified microorganisms (notified under document number C(2000) 2736) (Text with EEA relevance) Official Journal L 258 , 12/10/2000 p. 43 – 48.
- **COUNCIL DIRECTIVE 98/81/EC** of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified microorganisms. Official Journal L 330 , 05/12/1998 p. 13 – 31.
- **COUNCIL DIRECTIVE 90/219/EEC** of 23 April 1990 on the contained use of genetically modified microorganisms. Official Journal L 117, 08/05/1990 p. 1 – 14.

Protection of Workers Exposed to Biological Agents at Work

- **DIRECTIVE 2000/54/EC** of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work. Seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC (OJ Journal L 262, 17/10/2000 p. 21 – 45).
 - Directive 2000/54/EC codifies Directive 90/679/EEC as well as its successive amendments. It therefore repeals these different Directives and replaces them.
- **Council Directive 89/391/EEC** of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29/06/1989 p. 1 – 8).
 - Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (Official Journal L 374 – 31.12.1990).

Amended by the following acts:

- Council Directive 93/88/EEC of 12 October 1993 (Official Journal L 268 of 29.10.1993)
- Commission Directive 95/30/EC of 30 June 1995 (Official Journal L 155 of 06.07.1995)
- Commission Directive 97/59/EC of 7 October 1997 (Official Journal L 282 of 15.10.1997)
- Commission Directive 97/65/EC of 26 November 1997 (Official Journal L 335 of 06.12.1997)

Advisory Boards

Scientific Committee on Health and Environmental Risks

Examines questions relating to examinations of the toxicity and ecotoxicity of chemicals, biochemicals and biological compounds whose use may have harmful consequences for human health and the environment.

The Committee will address questions in relation to new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipe work (e.g. new organics substances), drinking water, indoor and ambient air quality. It will address questions relating to human exposure to mixtures of chemicals, sensitisation and identification of endocrine disrupters.

Scientific Committee on emerging and Newly-Identified Health Risks

Examines questions concerning emerging or newly-identified risks and on broad, complex or multi-disciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk-assessment bodies.

As of this writing, it has been impossible to discuss with representatives of this Committee, formally or informally, for personal attribution or on background, whether this Committee has included synthetic biology in its work and what is its assessment of the potential risks and dangers associated with this new scientific developments.

Policy-Making/Regulatory Bodies

Directorate General – Health and Consumer Protection, Directorate Public Health – Risk Assessment

France

Statutory Framework

- **CODE DE L'ENVIRONNEMENT (Partie Législative)**
 - Livre V: Prévention des pollutions, des risques et des nuisances
 - Titre III: Organismes génétiquement modifiés
 - Chapitre Ier: Dispositions générales
 - Chapitre II: Utilisation confinée des organismes génétiquement modifiés
 - Chapitre III: Dissémination volontaire et mise sur le marché d'organismes génétiquement modifiés
- **CODE DU TRAVAIL (Partie Législative)**
 - Livre II: Réglementation du travail
 - Titre III: Hygiène, sécurité et conditions de travail

Deliberate Release into the Environment of Genetically Modified Organisms

- **DIRECTIVE 2001/18/EC** of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)

Contained Use of Pathogenic and/or Genetically Modified Organisms

- **COUNCIL DIRECTIVE 98/81/EC** of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms. Official Journal L 330, 05/12/1998 p. 13 – 31.
- **COUNCIL DIRECTIVE 90/219/EEC** of 23 April 1990 on the contained use of genetically modified micro-organisms. Official Journal L 117, 08/05/1990 p. 1 – 14.

Protection of Workers Exposed to Biological Agents at Work

- **ARRÊTÉ DU 30 JUILLET 2004** relatif à la mise en oeuvre, l'importation, l'exportation, la détention, la cession à titre gratuit ou onéreux, l'acquisition et le transport de certains agents responsables de maladies infectieuses, micro-organismes pathogènes et toxines. (NOR: SANP0422322A - JO n° 182 du 7 août 2004 page 14114).
 - Decree concerning the use, importation, exportation, distribution (free or commercial), receiving and the transport of certain biological agents responsible for infectious diseases, pathogens and toxins.
- **ARRÊTÉ DU 18 JUILLET 1994** fixant la liste des agents biologiques pathogènes (NOR: TEFT9400844A - JO n° 175 du 30 juillet 1994 page 11078): list of pathogens.
- **DÉCRET NO 94-352 DU 4 MAI 1994** relatif à la protection des travailleurs contre les risques résultant de leur exposition à des agents biologiques et modifiant le code du travail (deuxième partie: Décrets en Conseil d'Etat - Section VI "Prévention du risque biologique"). (NOR: TEFT9400313D - JO n° 105 du 6 mai 1994 page 6620)
 - These and other regulatory measures are integrated in the “code du travail – partie réglementaire” as follows:
- **CODE DU TRAVAIL (Partie Réglementaire - Décrets en Conseil d'Etat):** Livre II: Réglementation du travail, Titre III: Hygiène et sécurité, Chapitre Ier , Section 6: Prévention du risque biologique:
 - Sous-section 1: Définitions
 - Sous-section 2: Règles générales d'évaluation et de prévention du risque biologique
 - Sous-section 3: Formation et information
 - Sous-section 4: Dispositions particulières à certaines activités
 - Sous-section 5: Surveillance médicale spéciale

Advisory Boards

- **Commission de Génie Génétique**

- The Law 92-654 of July 13, 1992 article 3-1 defines the Genetic Engineering Commission's mission (Commission de Génie Génétique, CGG) as follows (summary):
- The CGG is charged of evaluating the risks and dangers created by genetically modified organisms and the procedures used for their creation, as well as the potential risks and dangers associated with the use of genetic engineering technologies.
- Concerning the contained use, the CGG proposes containment measures to prevent the risks associated with the use of GMOs, of procedures and techniques.

Regulatory Authority

- Ministère de la santé et de la protection sociale
- Centre national de la recherche scientifique / Ministère chargé de la recherche
- Ministère de l'agriculture, de l'alimentation, de la pêche et des affaires rurales

Germany

Statutory Framework

- **GENTECHNIKGESETZ (GenTG) 1993:** govern all uses of genetically modified organisms except for human applications.
- **GESETZ zur Anpassung von Zuständigkeiten im Gentechnikrecht 2004:** describes changes in regulatory authority as required by the "Gentechnikrecht 2004".
- **EG-GENTECHNIK-DURCHFÜHRUNGSGESETZ (EGGenTDurchfG) 2004:** statute governing the implementation of EU regulations pertaining to biotechnology.

Deliberate Release into the Environment of Genetically Modified Organisms

- **VERORDNUNG über Aufzeichnungen bei gentechnischen Arbeiten und bei Freisetzungen (Gentechnik-Aufzeichnungsverordnung – GenTAufzV) 1996:** Regulation establishing mandatory protocols for conducting genetic manipulations and for the release of genetically modified organisms (BGBl. I S. 1645 – 4. November 1996)

Contained Use of Pathogenic and/or Genetically Modified Organisms

- **VERORDNUNG über die Erstellung von außerbetrieblichen Notfallplänen und über Informations-, Melde- und Unterrichtspflichten (GenTNotfV) 1997:** regulation for the implementation of community emergency plans. Also establishes information and reporting requirements (BGBl. (Bundesgesetzblatt) I S. 2882 – 10. Oktober 1997)
- **VERORDNUNG über Anhörungsverfahren nach dem Gentechnikgesetz (Gentechnik-Anhörungsverordnung – GenTAnhV) 1996:** regulation mandating public hearings for the establishment or modification of commercial facilities conducting safety level 3 or level 4 activities (BGBl. I S. 1649 – 4. November 1996)
- **VERORDNUNG über die Sicherheitsstufen und Sicherheitsmaßnahmen bei gentechnischen Arbeiten in gentechnischen Anlagen (Gentechnik Sicherheitsverordnung – GenTSV) 1995:** defines safety levels and describes safety measures (BGBl. I S. 297 – 14. März 1995)

Advisory Boards

Zentrale Kommission für die Biologische Sicherheit

The “central commission for biosafety” is an expert body charged with examining possible risks for humans, animals and the natural environment. associated with genetically manipulated organisms. Established by the “Gentechnikgesetz” §§ 4 und 5 regulation ZKBSV.

- **VERORDNUNG über die Zentrale Kommission für die Biologische Sicherheit (ZKBS-Verordnung – ZKBSV) 1996:** creates a “biosafety commission”, describes its duties and responsibilities, and establishes procedural norms (BGBl. I S. 1232 – 5. August 1996).

Protection of Workers Exposed to Biological Agents at Work

- **VERORDNUNG zum Schutz vor Gefahrstoffen (Gefahrenstoffverordnung – GefStoffV) 2005:** Article 8 of this regulation affects BioStoffV with regard to the definition of affected individuals, procedures of risk assessment, employee information and medical record-keeping requirements.
- **VERORDNUNG über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit biologischen Arbeitsstoffen (Biostoffverordnung BioStoffV) 1999:** implements EU directive 90/679/EEC of November 1990 (seventh individual directive within the meaning of article 16(1) of directive 89/391/EEC) (BGBl. I S. 50 – 27. Januar 1999)

Regulatory Authority

- Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)

Italy

Deliberate Release into the Environment of Genetically Modified Organisms

- **DECRETO LEGISLATIVO 8 luglio 2003, n.224:** Attuazione della direttiva 2001/18/CE concernente l'emissione deliberata nell'ambiente di organismi geneticamente modificati: implements EU Directive 2001/18/EC regulating the intentional release of genetically modified organisms.

Contained Use of Pathogenic and/or Genetically Modified Organisms

- **DECRETO LEGISLATIVO 12 aprile 2001, n. 206:** attuazione della direttiva 98/81/CE del Consiglio che modifica la direttiva 90/219/CEE concernente l'impiego confinato di microorganismi geneticamente modificati: implements EU Directive 98/81/EC governing the contained use of genetically modified organisms.

Protection of Workers Exposed to Biological Agents at Work

- **DIRECTIVE 2000/54/EC** of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work. Seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC (OJ Journal L 262, 17/10/2000 p. 21 – 45): this directive replaces and therefore repeals directive 90/679/EEC.
- **DECRETO LEGISLATIVO 19 settembre 1994 n. 626:** Attuazione delle direttive 89/391/CEE, 89/654/CEE, 89/655/CEE, 89/656/CEE, 90/269/CEE, 90/270/CEE, 90/394/CEE e 90/679/CEE riguardanti il miglioramento della sicurezza e della salute dei lavoratori sul luogo di lavoro.
 - As the title implies, this legislative decree implements several major individual EU directives designed to improve worker health and safety. As discussed in section xx above, directive 89/391/EEC establishes a general framework for maintaining health and worker safety, while directive 90/679/EEC deals specifically with biological risks.

Advisory Boards

- **Commissione interministeriale di valutazione**

- The “Comitato Nazionale per la Biosicurezza e le Biotecnologie (CNBB)”, i.e. the National Committee for Biosafety and Biotechnologies has been established by decree in 2001 (decreto istitutivo del Comitato per la Biosicurezza e le Biotecnologie – DPCM 14.XI.2001).
- This committee does more than just discharging the functions described in EU directive 98/81/EC Art 14. It performs numerous coordination functions and is also responsible for evaluating possible health and safety risks from the release of genetically manipulated organisms in the environment. Enabling legislation:

Regulatory Authority

- Ministero della Sanità (Health Ministry): Contained use of GMOs
- Ministero dell’Ambiente e della Tutela del Territorio (Ministry of the Environment): Intentional release of GMOs.

Switzerland

While Switzerland technically is not a member of the European Union, it actively collaborates with the Union in numerous policy areas, including science and technology policy. Switzerland has a long-standing policy of crafting “euro-compatible” legislation. This means that laws and regulations are routinely checked for their consistency with European norms. Furthermore, in the area of synthetic biology Swiss scientists (or scientists operating at Swiss Universities) play a key role. In addition, Switzerland is represented with one expert on the Committee on emerging and Newly Identified Health Risks. Finally, there is some evidence that of all European countries Switzerland is the only one that has begun informally exploring possible societal consequences of synthetic biology.

Statutory Framework

- **BUNDESGESETZ vom 21. März 2003 über die Gentechnik im Ausserhumanbereich (Gentechnikgesetz, GTG):** legal framework governing the creation and use of genetically modified organisms (medical applications excluded)
- **BUNDESGESETZ über die Bekämpfung übertragbarer Krankheiten des Menschen (Epidemiengesetz) vom 18. Dezember 1970:** prevention and mitigation of communicable diseases.
- **BUNDESGESETZ über den Umweltschutz (Umweltschutzgesetz, USG) vom 7. Oktober 1983:** protection of the natural environment.

- **BUNDESGESETZ über die Unfallversicherung (UVG) vom 20. März 1981:** statute governing the personal injury insurance.
- **VERORDNUNG vom 20. November 1996 über die Eidgenössische Fachkommission für Biologische Sicherheit**

Deliberate Release into the Environment of Genetically Modified Organisms

- **VERORDNUNG über den Umgang mit Organismen in der Umwelt (Freisetzungsverordnung, FrSV) Entwurf vom 21. November 2005:** proposed revision of the FrSV
- **VERORDNUNG vom 25. August 1999 über den Umgang mit Organismen in der Umwelt (Freisetzungsverordnung, FrSV):** regulates the release of genetically modified organisms in the natural environment.

Contained Use of Pathogenic and/or Genetically Modified Organisms

- **VERORDNUNG vom 25. August 1999 über den Umgang mit Organismen in geschlossenen Systemen (Einschliessungsverordnung, ESV)**

Protection of Workers Exposed to Biological Agents at Work

- **VERORDNUNG vom 25. August 1999 über den Schutz der Arbeitnehmerinnen und Arbeitnehmer vor Gefährdung durch Mikroorganismen (SAMV)**

Advisory Boards

- **Eidgenössische Fachkommission für biologische Sicherheit (EFBS)**
 - Federal Expert Commission for Biological Safety. This commission advises the government and the administration on health and safety issues. It also delivers technical opinions on proposal for conducting experiments on GMOs and pathogens. Statutory authority for the establishment of this commission are the Umweltschutzgesetz and the Epidemiengesetz and the Gentechnikgesetz. The commission work is governed by the following regulation:
- **Eidgenössische Ethikkommission für die Biotechnologie im Ausserhumanbereich (EKAH)**
 - Federal Ethics Commission for Biotechnology (medical applications excluded). EKAH is an independent commission created by the Swiss government in 1998 to advice the government and the administration on the ethical aspects of “green” biotechnology. Established by government decree, its involvement in the

authorization of contained uses and releases of GMOs is governed by the
Einschliessungsverordnung and the Freisetzungsverordnung (see below).

Regulatory Authority

- Bundesamt für Umwelt (BAFU) (Federal Agency for the Environment)
- Bundesamt für Gesundheit (BAG) (Federal Health Agency)

Entry Points

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United Kingdom

Statutory Framework

- **Environmental Protection Act 1990 (c. 43) 1990 c. 43:** Part VI – Genetically Modified Organisms
- **Health and Safety at Work Act 1974**

Deliberate Release into the Environment of Genetically Modified Organisms

- **Genetically Modified Organisms (Deliberate Release) Regulations 2002** – Statutory Instrument 2002 No. 2443
- **The Genetically Modified Organisms (Deliberate Release and Risk Assessment-Amendment) Regulations 1997** – Statutory Instrument 1997 No. 1900
- **Environmental Protection Act 1990 (c. 43) 1990 c. 43:** Section 108(1)

Contained Use of Pathogenic and/or Genetically Modified Organisms

- **The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005** – Statutory Instrument 2005 No. 2466
- **The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002** – Statutory Instrument 2002 No. 63
- **The Genetically Modified Organisms (Contained Use) Regulations 2000** – Statutory Instrument 2000 No. 2831
- **The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996** – Statutory Instrument 1996 No. 1106

Protection of Workers Exposed to Biological Agents at Work

- The Control of Substances Hazardous to Health (Amendment) Regulations 2004 - Statutory Instrument 2004 No. 3386
- The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2004 – Statutory Instrument 2004 No. 568
- The Control of Substances Hazardous to Health Regulations 2002 – Statutory Instrument 2002 No. 2677
- The Management of Health and Safety at Work Regulations 1999 – Statutory Instrument 1999 No. 3242

Competent Authorities

The Health and Safety Executive (HSE) and the Secretary of State for the Department for Environment, Food and Rural Affairs (Defra) form the Competent Authority in England and Wales for GMO(CU).

Advisory Boards

Advisory Committee on Releases to the Environment (ACRE)

- ACRE is an independent Advisory Committee composed of leading scientists. Its main function is to give statutory advice to Ministers in the UK on the risks to human health and the environment from the release and marketing of genetically modified organisms (GMOs).
- ACRE is a statutory advisory committee appointed under section 124 of the Environmental Protection Act 1990.
- The Committee works within the legislative framework set out by Part VI of the EPA and the GMO Deliberate Release Regulations 2002 which together implement Directive 2001/18/EC.

Scientific Advisory Committee on Genetic Modification (Contained Use) (SACGM(CU))

- The Scientific Advisory Committee on Genetically Modified Organisms (Contained Use) - SACGM (CU) - provides technical and scientific advice to the UK Competent Authorities (UK CAs) on all aspects of the human and environmental risks of the contained use of genetically modified organisms (GMOs). In particular:
 - To advise on the technical issues on individual activities notified under the Genetically Modified Organisms (Contained Use) Regulations 2000;
 - To provide advice on risk assessments for contained use activities involving GMOs; and
 - To develop and update guidance on all aspects of contained use of GMOs including the Compendium of Guidance.
 - The SACGM(CU) was set up as a Government scientific advisory committee in accordance with the Office of Science and Technology's Code of Practice for scientific advisory committees and operates in accordance with the Nolan principles.