ANNEX

R&D RELATED TO HEALTH, INFORMATION AND COMMUNICATION TECHNOLOGY (ICT) AND BIOTECHNOLOGY

1. This annex presents three areas of R&D for which it is not possible to derive information through direct use of the classifications recommended elsewhere in the Manual. All three are of high policy relevance, and there is a clear need for data on R&D related to these fields. To obtain the necessary data, it is often necessary to combine R&D data from various classifications or even to develop new survey questions.

A. Deriving data on health-related R&D from regular R&D statistics

Introduction

2. Recently, demand for data on health-related R&D has been particularly strong. As international comparisons are often requested, this section provides general guidance on how to compile data on health-related R&D from existing surveys and more general sources. In this context, "health-related" refers not only to biomedical research but also to a wider category including relevant R&D in the social sciences, notably on health services.

3. The aim of the exercise is to establish gross expenditure on R&D (GERD) for health, broken down by sector of performance and source of funds. There should be matching R&D personnel data by sector of employment. Guidance is also given on GBAORD, as those who seek health R&D series often use this source. Further information on international comparisons and examples of national efforts can be found in *Measuring Expenditure on Health-related R&D* (OECD, 2001).

4. In principle, similar compilations could be made for other fields such as agriculture.

1. General approach

5. There is demand for a data set covering all health-related R&D, but regular R&D surveys normally break down expenditure and personnel according to the primary aim/field/industrial activity of the unit concerned. Furthermore, classifications may not be detailed enough to identify small categories of health-related units.

6. The process thus has to be to break out the data for categories that are clearly health-related (core elements) and then to use various adjustment and estimation methods to refine these data and to add in the health-related component of other categories. This generally means starting from institutional classes, for which a full set of data is available (sources of funds, personnel, etc.) and then using functional data to make the necessary adjustments. The process will vary among sectors and also among countries because different institutional and functional breakdowns may be used and also because data providers have special knowledge of national specifics in the organisation of health R&D.

7. In principle, the preferred source should be GERD data reported by performers. In practice, several sources may be used to compile health-related R&D spending. In some countries, especially those where the collection of GBAORD data is associated with the general R&D survey, these budget series (particularly those for which data on first destination are compiled) may identify central government funds for R&D on health which are not immediately visible in the survey of performers by socio-economic objective (protection and improvement of human health) or field of science (medical sciences). Similarly, useful additional information and data may be gleaned from the reports of medical charities, health research councils and funds and even from the reports of pharmaceutical industry associations. Building up a reasonable picture of GERD for health may involve mixing and matching data from a variety of sources.

2. Identifying health-related R&D in GBAORD

8. Those seeking data on government funding of health-related R&D are often drawn to GBAORD because there is a specific category of socio-economic objective for this topic. However, they may not realise that this category only covers R&D whose primary purpose is the protection and improvement of human health (NABS 4) and that funds for relevant activities may be included in other categories.

9. The most important additional category is "general university funds and non-oriented research". The core coverage recommended for health in GBAORD is therefore:

- Health.
- General University Funds and Non-oriented research: medical sciences.

10. Health-related research funded for other objectives, for example military medical research, health and safety research at nuclear establishments or support for relevant enterprise R&D as part of industrial policy should also be included when available.

11. Countries that collect and report two-digit NABS data to Eurostat may include two subcategories of aid to industry:

- Manufacture of pharmaceutical products (NABS 0742).
- Manufacture of medical and surgical equipment and orthopaedic appliances (NABS 0791).

12. Perhaps the most important gap is the health-related R&D included in general university funds or non-oriented research elsewhere than in the medical sciences, especially in the biological sciences. Where any R&D funded by health research councils or similar research programmes is included in non-oriented research, it may be possible to identify the health-related element of biology to be included in health.

Table 1. Identifying health-related R&D in GBAORD

One-digit NABS	For countries using detailed NABS
Protection and improvement of human health	All
Non-oriented research	Medical sciences
General university funds	Medical sciences
Industrial production and technology	Support for the pharmaceutical industry Support for the medical instrument industry

13. Health-related R&D data derived from GBAORD give an incomplete picture of total public funding of such R&D, as GBAORD only covers the central government budget. Some health R&D may be funded by extra-budgetary public sources such as social security funds. Provincial and local government may fund health R&D, particularly when they are responsible for higher education or for general hospitals. Where these sums are significant, an effort should be made to add them to the data derived from GBAORD in order to obtain a figure for total government funding of health-related R&D.

3. Building GERD for health

3.1 The business enterprise sector

14. There are two manufacturing ISIC categories mainly relevant to health:

- 2423 Pharmaceuticals.
- 3311 Medical instruments.

15. Taken together, these can be considered the core components of health-related R&D, although medical instruments may require special extraction in the first instance. A full set of data should be available for each, thus making it possible to compile data on total intramural R&D by source of funds and R&D personnel by occupation/qualification.

16. Health-related R&D also takes place in the health services industry itself.

- 851 Human health activities, notably:
  - 8511 Hospitals.
  - 8519 (part) Testing laboratories, medical, analytical or diagnostic.

17. These may not be included in the R&D survey at all, especially if the health services are mainly public. If they are included, they will probably require special extraction. The extraction should also cover sources of funds and R&D personnel.

Table 2. Health R&D from performer-reported data: business enterprise sector

Category	**Source**
Pharmaceutical industry (ISIC rev. 3, 2423)	Possible to derive from R&D surveys either as industry group or product field
Medical instruments (ISIC rev. 3, 3311)	Requires special extraction from R&D surveys either as industry group or product field
R&D on pharmaceuticals performed in other industries	May be possible to derive from product field classification, other functional classification or extramural R&D expenditure of pharmaceutical industry
R&D on medical instruments performed in other industries.	May be possible to derive from product field classification, other functional classification or extramural R&D expenditure of medical instruments
Private health services (ISIC rev. 3, 851)	Extract if included in the scope of R&D surveys
R&D in other industries done for private health services	May be possible to distinguish if health services are a separate product group or from extramural R&D expenditures of private health services

18. Health-related R&D may be carried out in the services for the pharmaceutical, medical instrument and health service industries, notably in the R&D industry and the IT services industry (and indeed in medical analytical and testing laboratories). The best way of identifying the health R&D component is via cross-tabulation of industries and product fields. This should reveal in particular how much pharmaceutical R&D is being done outside the industry itself and also whether firms classified in the pharmaceutical industry are engaged in R&D on other products. Estimates must be made of the sources of funds of the additional health-related R&D in the services and of the R&D personnel concerned. Where product field data are not available, other series might be examined for additional information on health-related R&D, including R&D by field of science (medical sciences) R&D by socio-economic objective (health as SEO) or extramural expenditure by the pharmaceutical and medical instrument industries. Care should be taken to ensure that relevant R&D by biotechnology companies is included.

3.2 R&D in the non-market sectors (government, private non-profit, higher education)

19. Some countries undertake a standard survey of all R&D institutes, and these are subsequently divided among Frascati sectors of performance. Others undertake separate surveys for each sector.

3.2.1 General approach

20. This manual proposes collecting data by field of science, such as *medical sciences*, as both an institutional and a functional classification, and by socio-economic objective, with *health* as a functional classification.

21. Experience shows that neither health as a socio-economic objective nor the medical sciences as a field of science is enough to describe adequately the field of health-related R&D. A combination is needed, as shown in Table 3.

Table 3. Identifying health-related R&D by field of science and socio-economic objective

	Fields of science and technology			
Socio-economic objectives	**Medical/health**	Biological	Other natural sciences and engineering	Social sciences and humanities
Protection and improvement of human health	**X**	**X**	**X**	**X**
Non-oriented research	X	?		
All other	X			

X = to be included.

22. The core consists of all R&D for health in the medical sciences and/or for health as an SEO (shown bolded in Table 3). Obtaining this depends on how the two classifications are applied in each country. In theory, where the field of science classification matches that in Table 3, there should be little R&D for health as an SEO which is not included under medical sciences. However, the classification is not entirely clear for genetics, hence the column for the biological sciences and the potential problem of identifying how much biological R&D undertaken as non-oriented research is health-related.

23. Deriving the sources of funds and calculating the R&D personnel data for such a combination may involve some estimations.

24. This functional or semi-functional approach can be supplemented or replaced by data sets based on national institutional classifications, local knowledge about the national health R&D system and additional material from funding sources. For example, a list of the core national performers of health-related R&D in the government and private non-profit (PNP) sectors can be established, and special extractions from their responses can be made.

3.2.2 Higher education

25. Where teaching establishments receive a detailed R&D questionnaire, health-related R&D data can be compiled in the same way as R&D for other surveyed units. However, they often do not receive such a questionnaire and the data are derived from responses to a simpler questionnaire or are compiled from administrative sources. Usually, but not always, there is a breakdown by major field of science.

26. The core category is thus medical sciences as an institutional category for which intramural expenditure, sources of funds and R&D personnel should be available. However, if the classification unit is large, *e.g.* the medical faculty, health-related R&D in other faculties, such as biological sciences and social sciences, may be left out. The R&D funds are usually divided into direct funds and GUF, and details may

be available on the institutional sources of the direct funds. Where direct research funds flow to non-medical faculties from a health research council, programme of a health department, a medical charity or the pharmaceutical industry, these can be added.

3.2.3 Private non-profit sector

27. The recommended institutional breakdown is by field of science, which is used in most countries that separate out the PNP sector. R&D expenditure in the medical sciences is thus the core coverage, and sources of funds and personnel data should also be available. In this sector, expenditure on the medical sciences is generally higher than expenditure on health as an SEO. There is not likely to be additional health-related R&D spending unless there are units classified in the social sciences that carry out health services R&D or general life science units classified in the natural sciences that carry out medical research.

28. Where there is no classification by field of science, the units concerned may have to be selected individually on the basis of local knowledge. This sector may include a significant number of research units belonging to medical charities and should not be ignored merely because it is small overall.

3.2.4 The government sector

29. The Manual does not recommend an institutional classification for this sector and the breakdown used is often based on national administrative categories. For this reason and because of international differences in the way health-related R&D is organised in the government sector, it is particularly difficult to propose standard methods of identifying health-related R&D in this sector.

30. Where data are collected on both field of science and SEOs, R&D spending on health as an SEO is often higher than spending for the medical sciences in this sector, particularly where the medical sciences are an institutional category and SEO is a functional category. For this sector, the core should be all institutional units whose principal R&D activity is health as an SEO and/or the medical sciences. Any R&D in the field and/or relevant SEO in other institutions should be added. The additional information may be derived from crossing institutional and functional classifications or from other sources, for example programme descriptions in R&D budgets, annual reports of institutions, etc.

3.2.5 Special institutional problems

31. Some countries have multidisciplinary research councils with R&D-performing units in the government or higher education sectors which are classified under non-oriented research as an SEO and which do not break down their expenditures on life sciences as recommended in this Manual. It is difficult to identify the health-related component of these funds, as they are often earmarked for basic research.

32. When obtaining funds for health-related R&D, it is useful to look at how hospitals are treated in the national R&D survey in terms of coverage and classification.

3.3 Aggregating GERD on health

33. In principle, GERD is obtained by adding health-related R&D in each of the four sectors of performance. Sources of funds are found by aggregating what each sector received from business enterprise, government, private non-profit (PNP), higher education and abroad for carrying out health-related R&D. At this stage, it may be useful to check figures against any funder-reported series and perhaps calculate a health GNERD (gross national expenditure on R&D). Differences are to be expected, but if there are major discrepancies, for example if medical charities report much higher research funding than appears in GERD on health as funded by the PNP sector, further enquiries may be worthwhile.

B. ICT-related R&D

34. In recent years, there has been quite intensive work at the OECD by the Working Party on Indicators of the Information Society (WPIIS) to develop statistics and indicators for the ICT sector or, more broadly, the information economy sector. The aim is to develop statistics and indicators that result in a better understanding of the information economy or the information society.

35. A fundamental milestone was the reaching of an agreement on a definition of the ICT sector based on ISIC Rev. 3. This definition identifies key industries whose main activity is producing or distributing ICT products or services and which constitute an approximation of the "ICT-producing sector". It needs to be complemented by a product-based definition.

36. The list of industries belonging to the ICT sector is as follows:

ISIC rev. 3	
Manufacturing	
3000	Office, accounting and computing machinery
3130	Insulated wire and cable
3210	Electronic valves and tubes and other electronic components
3220	Television and radio transmitters and apparatus for line telephony and line telegraphy
3230	Television and radio receivers, sound and video recording or reproducing apparatus, and associated goods
3312	Instruments and appliances for measuring, checking, testing, navigating and other purposes, except industrial process equipment
3313	Industrial process control equipment
Services	
5150	Wholesale of machinery, equipment and supplies (in ISIC Rev. 3.1 limited to class 5151 "wholesale of computers, computer peripheral equipment and software" and class 5152 "wholesale of electronic and telecommunication parts and equipment")
6420	Telecommunications
7123	Renting of office machinery and equipment (including computers)
72	Computer and related activities

37. This classification is a good starting point for defining ICT-related R&D in the business enterprise sector. In R&D surveys, data are often available only at ISIC 2-digit classifications. This makes direct application of this list difficult. In addition, some categories have rather limited ICT content (ISIC 3130) or are somewhat irrelevant for R&D surveys (*e.g.* the wholesale or renting categories). An operational definition of ICT-related R&D may therefore include ISIC 30, 32 and 33 (ICT-related R&D in manufacturing) and ISIC 64 and 72 (ICT-related R&D in services).

38. The above classification needs to be complemented by a classification that is more relevant for defining ICT-related research, *i.e.* a product field classification, which is a functional classification. Work is under way to reach an international recommendation on which product groups are to be regarded as ICT-related. Although the product field classification is not used in R&D surveys in every country, a definition in terms of product group, when agreed, may be more relevant for defining ICT-related R&D in the business enterprise sector. Chapter 4, Section 4.3, of the Manual now includes a more explicit recommendation on the use of a product group classification in R&D surveys. The product group is

defined according to the final product of the enterprise. This means, for example, that R&D performed by a car manufacturer for software included in cars will not be considered as ICT-related R&D, as the software is not the car manufacturer's final product. However, if the software is bought from an outside company, any R&D carried out by that company for the software product is considered ICT-related R&D.

39. One problem with using the product field classification could be that the level of aggregation of the product field classification used in R&D surveys may be too broad to distinguish ICT-related R&D that is defined according to very disaggregated product groups.

40. R&D that is relevant for ICT or, more broadly, for the information economy or information society also takes place in other sectors of performance. Here, the field of science classification is useful. However, the field of science classification recommended in Chapter 3 of the Manual is not very helpful for identifying ICT-related R&D. Work is to start to develop a new classification by field of science that is applicable for statistical purposes. It would be essential to identify under natural sciences and engineering, and probably also social sciences, subfields of relevance for the ICT sector or, more broadly, the information economy or information society. Examples are computer hardware, communication technologies and information, computing and communication sciences. The application of a very detailed field of science classification certainly causes difficulties in several countries. This will affect their possibilities for using the field of science classification to produce information on ICT-related R&D.

41. In theory, the socio-economic objectives (SEO) classification may also be used to distinguish ICT-related R&D. Relevant subclasses are included at the 2-digit level of the present NABS. However, the SEO classification is applied at this level of detail only in some EU countries.

C. Biotechnology-related R&D

Introduction

42. Biotechnology is perceived as having the potential to be the next pervasive technology of great significance for future economic development. Work is under way at the OECD to develop a statistical framework for the measurement of biotechnology activities and to identify more closely the needs of users for indicators on biotechnology activities and on the effects of biotechnology. On the basis of these considerations, a model survey of biotechnology is under development. As an aid, a definition of biotechnology, in terms of a single definition and a list of technologies, has been agreed as a basis for further work and is presented at the end of this annex.

Classifications

43. Classifications are usually used to delimit a field. Because biotechnology is a process as opposed to a product or an industry, it is not easily identifiable on the basis of existing classifications. ISIC, the standard international classification of economic activities, was revised during the 1980s when interest in biotechnology was rather limited. For the moment, it is not possible to identify specific biotechnology industries at any level of ISIC (division, group, class). Some preliminary discussions have taken place on the possibility of identifying biotechnology-related industries in the next major revision of the classification. The situation is more or less the same for the central product group classification (CPC) and the harmonised commodity description and coding system HS 2002.

44. In their present form, the more R&D-related classifications by field of science (FOS) and socio-economic objectives (SEO) are not suitable for the identification of biotechnology. Biotechnology is related to several of the major fields of science recommended in the Manual, including natural sciences, engineering, medical sciences and agricultural sciences. It may be possible to identify biotechnology on the

basis of a more detailed classification by field of science, including agreed subfields of the major fields of science. This has to be investigated during work to revise the field of science classification.

45. Experience in Australia indicates possibilities for identifying biotechnology-related R&D on the basis of a detailed field of science classification. The Australian classification has a specific category called "biotechnology", but there are also relevant categories at different levels of the classification, such as biochemistry and cell biology, genetics, microbiology, industrial biotechnology, bioremediation, biomaterials and medical biotechnology.

46. It will be difficult to identify biotechnology in any revised classification by socio-economic objectives.

Model surveys

47. The only possibility for obtaining information on biotechnology R&D or use of biotechnology is therefore to develop special surveys on biotechnology or to ask additional questions in existing surveys, such as the R&D survey. The first option is being explored in work to develop model surveys for biotechnology. The second option is to obtain information on biotechnology R&D from normal R&D surveys through use of the OECD definition of biotechnology.

Adding questions on biotechnology to R&D surveys

48. The following discussion addresses the issue of adding questions to an existing R&D survey.

49. Special questions on biotechnology to be added to R&D surveys or collected in connection with them have some limitations. These are:

- The variable should be included in the general R&D survey framework.
- Appropriate classifications should be available for describing biotechnology-related R&D.
- The additions on biotechnology should increase the response burden only marginally.

50. Some ten countries have experience in requesting information on the share of biotechnology R&D in total R&D expenditure. A question is often asked in the context of a list of interesting technologies, of which biotechnology is one. The surveys give a single definition, a list of relevant technologies or a combination of the two. The definitions used in various surveys differ. To improve comparability, it is recommended to use the OECD definitions (both the single definition and the list presented at the end of this annex). This would be the first step towards having more comparable data on biotechnology R&D.

The following type of question could be asked in the general R&D survey:

Did the R&D reported above include any biotechnology R&D (see definition)?

Yes ( )

No ( )

If yes, please provide an estimate of the share of the total intramural R&D expenditure reported earlier that is attributable to biotechnology. _____%

51. To guide the respondent, the OECD definition of biotechnology should be provided. The list-based definition may be more helpful, but both may be needed.

52. Another question that might be considered is the share of public funding of R&D going to biotechnology R&D. The detailed formulation of this variable may need further elaboration.

53. As the interaction between science and technology is particularly strong in the field of biotechnology, it is also recommended to include this kind of question for R&D surveys in the other Frascati sectors. The experience of a few countries suggests that this is feasible.

54. It is recommended to introduce a few simple questions on biotechnology R&D in R&D surveys in as many Member countries as possible to have a broader comparable overview of the role of biotechnology in their R&D efforts.

55. Biotechnology is a multidisciplinary field. This poses particular problems in categorising biotechnology for survey purposes. The current OECD definition of biotechnology is preliminary and has mainly been piloted in R&D surveys of the business enterprise sector. For comparability, the definition is also recommended for use in other sectors. The experience gained from using the definition in all sectors will lead to further revisions of the current definition.

OECD definition of biotechnology

56.

"The application of S&T to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."

The **(**indicative, not exhaustive**)** list-based definition is:

- DNA (coding): genomics, pharmaco-genetics, gene probes, DNA sequencing/ synthesis/ amplification, genetic engineering.
- Proteins and molecules (functional blocks): protein/peptide sequencing/synthesis, lipid/protein glyco**-**engineering, proteomics, hormones and growth factors, cell receptors/signalling/pheromones.
- Cell and tissue culture and engineering : cell/tissue culture, tissue engineering, hybridisation, cellular fusion, vaccine/immune stimulants, embryo manipulation.
- Process biotechnologies: bioreactors, fermentation, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation and biofiltration.
- Sub-cellular organisms: gene therapy, viral vectors.

OECD (2002), "R&D related to health, information and communication technology (ICT) and biotechnology", in *Frascati Manual 2002: Proposed Standard Practice for Surveys on Research and Experimental Development*,
The Measurement of Scientific and Technological Activities, OECD Publishing, Paris.
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