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Keywords: biotechnology company, bioethics, ethics committee, media, education, industry public relations

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How biotechnology companies respond to bioethical issues

Makina Kato and Darryl Macer Date received (in revised form): 18th September, 2002

Abstract

This paper presents the main findings of a research project that investigated how biotechnology companies in different countries address bioethical issues. The study comprised a questionnaire survey and a series of interviews with international organisations and academics in Japan, Europe and North America. While the research clearly indicated that a number of companies expected to have to address bioethical issues in the future, the results also demonstrated that there was a hesitance to admit that bioethical issues had caused problems in the past. The findings also established that companies responded to bioethical issues in different ways and some of the larger organisations were found to set up ethics committees and educate their employees more effectively on bioethical issues. The respondents were also concerned by the biased or distorted view provided by the media and felt it was important that objective information on this area was provided to the public.

INTRODUCTION

Companies and industry have been playing significant roles in the development of modern biotechnology for the past few decades. However, despite ubiquitous government encouragement of industry, various bioethical issues have been raised over the application and commercialisation of biotechnology. It is readily apparent that there is variety in the way different companies concerned with biotechnology deal with bioethical issues at present, and how those concerned are aware of these issues. However despite the growing number of company reports that promote bioethics,² with emphasis on the environment³ and promoting activities in the developing world, there are few papers presenting analysis of the various approaches used by companies.

Different countries have developed a range of laws in the fields of modern biotechnology, with interesting contrasts. For example, human embryo experiments are permitted in the UK but are a crime in Germany. Experiments using chimpanzees are not allowed in the EU

but are allowed in North America. Companies need a 'bioethics standard' to follow in order to reduce or even prevent bioethical problems, and promote their activity in better harmony with society.

The question of how many companies are taking these bioethics questions seriously can be answered in different ways. In this paper we explore the use of written surveys, and make some comparisons to interviews. Both methods are subject to response bias, meaning we may select companies that are willing to talk about this issue. This willingness might be because they have not had a particular problem and are interested, or because they want to learn from past 'mistakes'. In this paper the authors report how companies say that they deal with bioethical issues, and suggest directions for future research.

INTERVIEWS AND SURVEY

This paper presents relevant results of individual and group interviews, and a questionnaire survey. First, in-depth interviews were conducted with 42 people from September 2000 to June

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Interviews with experts were conducted

Questionnaires were

sent to CEOs of

companies

2002, in Japan, Europe and North America. The interviewees were selected experts in international organisations and bioethics academics, and selected persons in multinational and Japanese companies concerned with biotechnology. Additionally the contents of discussions in several academic and industry conferences on the theme were observed.

Secondly, based on the initial results of interviews, a questionnaire was developed and used in a pilot survey conducted among non-Japanese biotechnology companies. Questionnaires were posted by mail on 27th August, 2001, and the last response was received on 26th November. Some 559 companies where information about business operation and addresses was available were selected as targets from '1999–2000 World Bio Companies'. Since this was a pilot survey to measure the enthusiasm of companies towards these issues no reminders were sent.

The questionnaires were addressed to the President or CEO by name. These are the persons in top management positions of the companies. As the structure of companies differ from each other, the surveys were sent to the CEO. It was assumed that people in top management should have some understanding of ethical issues, and knowledge of how the company as a whole had approached the issues raised in the questionnaire.

The analysis methods employed in this study included: (1) quantitative analysis of Yes/No answers, (2) cross-tabulation of Yes/No answers and attributes of the companies (nationality, type of industry, number of employees and annual sales) and (3) qualitative analysis of comments expressed in interviews (from transcripts of tape recordings and/or notes) and questionnaires by the Card Work method.⁶

The Card Work method (or KJ Method) is basically inductive and consists of the following steps:

• First, resolve qualitative information such as remarks or sentences into

- essential elements, to analyse the essence of the information that is of different nature.
- Secondly, write each minimum unit that makes sense as an opinion on a card, as one 'element'.
- Thirdly, collect the cards of elements that have similar ideas and regroup them in common meanings of the elements itself.
- Fourthly, regroup these independent groups again in common meaning and repeat this several times as appropriate.
- Finally, make an overall summary of the total information.

Thus, the Card Work method provides an overview of given information and enables it to be sorted inductively. It is useful to examine the diversity of ideas. Rather than summarising points with a dogmatic way of thinking, the focus is on the similarity of elements of the information, to put information in positions related to similar ideas, in contrast to those that are different. It is a type of discourse analysis.

ATTRIBUTES OF THE TARGET COMPANIES SURVEYED

Most of the target companies were in the USA, 354 companies (63 per cent), and there were 59 (11 per cent) from the UK. In order next were France, Canada and Germany. By industry, those of Medicals and Diagnostics were the majority with 380 companies (68 per cent), followed by Research Devices and Reagents and Materials for Research with 70 companies (13 per cent). Subsequently there were those in the fields of Agriculture, Service, Chemistry and Electronics, Foods and the Environment.

The ratio of number of employees of the target companies are, respectively, 39 per cent small-to-medium companies with fewer than 100 persons, 39 per cent

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mid-size companies with fewer than 1,000 persons and 21 per cent big companies with more than 1,000 persons. The ratio of annual sales of the target companies are, respectively, 41 per cent small-to-medium companies with less than US\$10m, 31 per cent mid-size companies with less than US\$100m, and 28 per cent big companies with more than US\$100m.

ATTRIBUTES OF THE COMPANIES WITH VALID RESPONSES

The total number of responses to the mail survey was 85 and the response rate was 15 per cent. Among these replies, however, only 34 valid responses (6 per cent of the total) were received which included the completed questionnaire. A few companies sent brochures or materials as a substitute or in addition to the survey response. It is because of the low response rate that we consider this a pilot survey, but present the comments as they illustrate some important points that should be developed in further research on this subject.

Of the 51 companies who said that they would not complete the survey, by regular mail or e-mail, 18 per cent answered that they were not a 'biotech company'. Considering that some of these actually conduct R&D or have products related to biotechnology or living organisms, it is clear that the term 'biotech company' may cause different reactions among the companies, who may not associate themselves with that label.

A further 10 per cent of them said that the matters in this questionnaire were regarded as confidential. This shows that bioethics issues in some companies may be considered as confidential and may not be discussed outside, and are not published. Given the experience from interviews this may be the main reason that companies do not reply to this type of survey.

Looking at the nationalities of the companies with valid responses (N=34), 11 were from the USA (32 per cent), 7 from the UK (20 per cent), and there

were fewer replies from Canada and the Netherlands in that order. The ratio of US companies is lower compared with the population of targeted companies that were mailed. One of the reasons would be the effect of the terrorist attack on 11th September, 2001. By industry, those in Medical and Diagnostics were the most with 24 companies (70 per cent), those in the field of Research Devices and Reagents and Materials for Research were the second most well represented with 5 companies (15 per cent), with fewer from companies in Agriculture, Chemistry & Electronics, Environment in that order.

The ratio of number of employees of the companies with valid responses was not significantly different from those surveyed, with 45 per cent small-tomedium companies of fewer than 100 persons, 32 per cent mid-size companies of fewer than 1,000 persons and 23 per cent big companies of more than 1,000 persons. The ratio of annual sales of the companies with valid responses was, respectively, 47 per cent small-to-medium companies with less than US\$10m, 29 per cent mid-size companies with less than US\$100m and 25 per cent big companies with more than US\$100m, also similar to those surveyed. It was concluded that valid responses reflected the population of companies surveyed, except for the lower proportion of US companies. There was a tendency for more response from smallto-medium companies.

Nearly 30 per cent of the senders of the questionnaires were sent in the name of the president/CEO of the companies, and the rest of those named were from the vice-president level, under sections such as R&D and Public Relations. About 40 per cent of them did not write their names in the answers. The results of the survey are shown in Table 1 and there follows below a discussion of the key findings.

HESITANCE TO ADMIT BIOETHICAL PROBLEMS IN THE PAST

Although only 24 per cent of the survey respondents said their company 'had a

34 valid responses were analysed in depth

32 per cent were from the USA and 20 per cent from the UK

Some companies did not reply because the questionnaire asked questions about bioethics which they thought touched on confidential matters

Table 1: Results of questionnaire surveying attitudes of international companies on bioethical issues

Question	Response (% of total)		
	Yes	No	N/A
Do you think in the future you could have a bioethical problem related to biotechnology in your company?	47	50	3
Do you have any special measures or systems in your company to deal with bioethical issues related to biotechnology?	44	53	3
Do you have any special code of ethics or guidelines concerning bioethics?	38	59	3
Especially in the research and development stage, do you have any system in your company to deal with bioethical issues?	41.20	47.10	11.80
Especially in the sales and marketing stage, do you have any system in your company to deal with bioethical issues?	26.50	64.70	8.80
Do you educate your employees in bioethics?	29.40	67.60	2.90
Do you have any communication or education for consumers on your biotechnology research?	44.10	50.00	5.90

Only 24 per cent admitted to a bioethical problem in the past

The most commonly cited ethical problems involved animal research

Half of those who responded thought they would face a bioethical problem in the future bioethical problem related to biotechnology in the past', and 71 per cent said it had not, there was a diversity of problems mentioned in the comments. More companies in the field of medicine, and more small-to-medium or mid-size companies, considered they had had such problems, than larger companies. In the interviews, respondents were more likely to say they had a bioethical problem in the past, even when not directly asked about it.

The comments in the questionnaire survey were more revealing. These ranged from ethical issues of technology itself, such as use of human biological material and use of animals, to safety of products. The comments in questionnaires could be separated into three groups, as below, with some illustrative examples of open comments:

- Have had specific problems: 'The use of healthy animals for experimentation; it meant the euthanization of healthy dogs. We did not use healthy animals, after all.'
- Have not had ethical problems: 'We are very interested in the subject and conduct our work in a uniformly fashion.'
- You should define 'problem': 'You should define the term problem!'

The most common issues mentioned by the companies were ethical problems about experimental or commercial use of animals. There were five such elements included, when analysed by the Card Work method, from four companies. A further two companies mentioned about xenotransplants. Three companies mentioned ethical issues regarding human biological materials, two mentioned product safety, two mentioned clinical trials and one mentioned priorities for drug research for the developing world.

EXPECTATION OF MORE BIOETHICAL CONCERNS IN THE FUTURE

Half of the survey results, 47 per cent, said that they thought they 'could have a bioethical problem related to biotechnology in the future', and 50 per cent said they could not. Judging from the comments to this question, however, those who are involved in dealing with biological materials or genetic information foresee certain bioethical problems with some trepidation. Looking at the tendency of the answers by nationality, concerns about bioethical problems in the future were expressed more in US companies.

The comments in questionnaires were

more revealing, and could be separated into four groups, as below, with some illustrative examples of open comments:

- Think that general problems will occur: 'All innovations are potentially associated with ethical concerns (foreseen or not).'
- Think that specific problems will occur: 'Genetic tests could create issues for patients, such as whether or not that person could receive insurance, and whether or not there is any therapeutic intervention available for a given diagnosis.'
- Could have problems but cannot see what will occur: 'Possible, but right now I don't see any on the horizon.'
- Do not think they could have problems: 'Probably, none we will consider each case on its merits diagnosis.'

Four elements were mentioned about human biological materials, from two companies. Three companies mentioned genetic tests and genetic information. Three companies mentioned product safety, three mentioned experimental use of animals, two mentioned clinical trials and two mentioned provision of drugs. These issues were also mentioned in the interviews.

Among the four companies that answered they do not think they could have problems, two said that they could deal with the issues adequately, and the other two said that they are unrelated to the issues.

DIVERSITY OF APPROACHES

When asked whether they had any special measures or systems in their company to deal with bioethical issues related to biotechnology, 44 per cent said they had and 53 per cent said they did not. The proportion of those who answered that they had such measures or systems was higher in big companies than in small-to-medium and mid-size companies. Further, even among those who answered

they had measures or systems there were varieties of ways and levels of dealing with issues. Bioethical issues in companies have been dealt with not only in the special measures or system for bioethics but also in the conventional or other systems such as crisis management.

The comments in questionnaires were more revealing, and could be separated into three groups, as below, with some illustrative examples of open comments:

- Have a special system for bioethics and deal with issues in it: 'A bioethical committee composed of internationally recognized bioethicists.'
- Have codes of ethics or policy statements: 'We have general policy statements about types of products we will and will **not** undertake.'
- Deal with issues in the systems not especially for bioethics: 'Our quality assurance team continuously monitors any ethical issues.'

Six companies answered that they had a special system for bioethics, such as a bioethics committee, ethics committees and institutional review boards (IRBs). In interviews, some mentioned the establishment of such ethics committees and committees related to clinical trials. The most common other measures mentioned by the companies were dealing with the issues in the systems for crisis management and quality assurance. There were five such elements from five companies. Four companies answered they had systems such as research reviews. Three companies mentioned conformity to regulations by nations or industry organisations, and two said they examined each case internally.

STANDARDS IN R&D ALREADY EXIST

When asked whether they have any system 'especially in the research and development stage', 41 per cent said they had such a system and 47 per cent said

44 per cent said they had special measures to deal with bioethical issues UK companies showed more positive efforts to implement bioethical systems for R&D

Some companies said

that they rely on good

judgment and common

they did not. These efforts stood out in small-to-medium companies that more focused on research or specialty, but among them there were some companies that coped with issues not in the system especially for bioethics but in the conventional review system for R&D. In addition, it was clear that some companies consider it sufficient to have awareness in their practical works even without any formal system. In all the countries surveyed there are external regulations on their work and companies had to follow them. Looking at the tendency of these answers by nationality, 43 per cent of those who answered 'Yes' were UK companies, which showed more positive efforts to such systems in the UK.

The comments in questionnaires were more revealing, and could be separated into five groups, as below, with some illustrative examples of open comments:

- Follow external regulations of such as nations and industry organisations: 'Governmental regulation demands the permit of ethic committee, experimental animal committee, and regional chief veterinarian before any project can be started.'
- Have ethics committees and deal with the issues here: 'We have an ethics committee with one outside expert to join the company team.'
- Check or review in some ways: 'Review of scientific progress; internal review by peers.'
- Cope with the issues with awareness in the work even without formal systems: 'We rely on good judgment and common sense.'
- Do not think the problem will occur: 'Note bioethical issues do not normally occur. The concern is more about the reliability of the product for its intended use in the diagnosis of disease studies in humans.'

Overall, seven companies mentioned that they follow the external regulations of their government or industry organisations. Only five companies said they had ethics committees, six said they check or review in some ways and six said they cope with issues with awareness even without formal systems. In addition, three companies said they do not think the problem will occur.

STANDARDS IN SALES AND MARKETING

As for the system to deal with bioethical issues 'especially in the sales and marketing stage', 27 per cent said they had such systems and 65 per cent said they did not. It showed companies related to biotechnology, as a whole, were not very positive about such systems. As research and development are emphasised in the biotechnology industry, there were some companies saying that they had not yet had products and that this question was not applicable for them, while only three companies mentioned concrete internal systems especially in the sales and marketing (S&M) stage. It also signified less positive efforts to systems especially in the S&M in small-to-medium companies that were more focused on research or a specialty. Further, more positive efforts to such systems were seen in the UK.

The comments in questionnaires were more revealing, and could be separated into six groups, as below, with some illustrative examples of open comments:

- Follow external regulations of such as nations and industry organisations:
 'Essentially we follow what regulations and competent authorities recommend.'
- Have systems especially in the stage of sales and marketing: 'All new customers must provide acceptable reasons for requiring our products.'
- It is included in the whole systems for bioethical issues or other systems: 'Part of Feasibility on Product Design documents (related to ISO 9000).'

sense

- Discuss the issues internally: 'Corporate debate.'
- Do not have any systems because we are not at the stage of products: 'We have no products at that stage.'
- This question is not applicable: 'Question is not applicable.'

Only four companies mentioned following external regulations, and three companies said they had systems, especially in the S&M stage. On the other hand, five said it is included in the whole systems for bioethical issues or other systems and two said they discussed these issues. Besides, three answered they were not at that stage of products and two answered the question was not applicable for them.

VARIETY OF EFFORTS TO COMMIT A COMPANY STANDPOINT TO PAPER

In the next question, 38 per cent said they had special code or guidelines concerning bioethics and 59 per cent said they did not. Judging from the comments, however, 'codes' or 'guidelines' took various forms, including code of ethics, guidelines and policy statement. These were not only the ones developed internally but the regulations or guidelines of nations and industrial organisations were employed as well. There was a tendency for more positive responses to this question from companies in the UK than in the USA. It clearly signified the difference between these two countries in the efforts about code of ethics or guidelines related to bioethics. Such efforts to commit the company position to a written statement were advanced mainly in big companies. In addition, there were two companies who said they did not need such a code of ethics or guidelines but they were a minority.

The comments in questionnaires were more revealing, and could be separated into seven groups, as below, with some illustrative examples of open comments (the numbers indicates the number of elements followed by the number of companies):

- Have codes of ethics or guidelines related to bioethics (4-4): 'Guidelines related to specific issues, eg animal welfare, biodiversity, stem cell research.'
- Have policy or policy statement on the issues concerned (4-4): 'We do have an animal welfare policy.'
- Have general codes of ethics or code of codes of conduct not especially about bioethics (3-2): 'Code of Conduct, not specifically linked to bioethics.'
- Follow codes, guidelines or policies of industry organisations to which they belong (5-5): 'Follow Bio Industries Association Code of Ethics.'
- Conform to regulation or guidelines of nations and regions (6-6): 'Not really except that a number of rules matching national recommendations are being enforced, eg no experiments using "human genes" or even genes that are originally cloned from mammals.'
- Do not have any internal codes of ethics or guidelines (2-2): 'We are still a very small company and have not formalised a code of bioethics.'
- Do not need any internal codes of ethics or guidelines (2-2): 'We judge ethical cases one by one on their merits.'

GREAT DIVERSITY OF EMPLOYEE BIOETHICS EDUCATION

Overall, 29 per cent said they educated their employees in bioethics and 68 per cent said they did not. It signified that nearly 70 per cent of them did not have any employee education in bioethics. There were great differences in such education among companies related to biotechnology. Some companies held special lectures or workshops, or trained internal experts, while others did not feel a need since they

Less bioethics systems in the S&M stage than R&D

38 per cent had a special code or guidelines concerning bioethics

Committing the company's bioethics position to paper requires a sense of responsibility which some companies cannot commit themselves to, or simply do not have the resources to spend time in its preparation

29 per cent said they educated their employees in bioethics, but 68 per cent said they did not trusted their employees' high awareness. Four companies out of six that mentioned a employee education were big companies whose number of employees were over 20,000, and more positive efforts were found in big companies. Actually, 80 per cent of those who answered 'Yes' were European companies.

The comments in questionnaires were more revealing, and could be separated into four groups, as below, with some illustrative examples of open comments:

- Have concrete employee education related to bioethics: '2–3 seminar sessions/year (usually on Saturday) where we invite 2–3 Bioethics luminaries (all academics) to address us, then engage in dialogue with the staff. We have done this 3 times in last year with 20–50 staff attending voluntarily. The chairperson of this effort is an Academic Bioethicist.'
- Educate employees with own codes of conduct: 'We follow an internal 'code of conduct'.' This includes policies on various aspects including bioethics.'
- Bioethics education for employees is included in other internal systems: 'It is integrated into our quality assurance system.'
- Do not have such an education because it is not needed: 'Not specifically. Everyone thinks about the issues.'

The most common comments were expressing that they do not have such an education because there was no need, mentioned by eight companies. Next, six companies mentioned concrete employee education related to bioethics, while two mentioned education with own codes of conduct and further two said that it is included in other internal systems.

CONCERNS OVER BIOETHICAL ISSUES AND FEARS OF OVERREACTION BY THE PUBLIC

Less than half, 44 per cent, of the companies said they had 'communication

or education for consumers in biotechnology' and 50 per cent said they did not. There were not any companies who answered that such communication were unnecessary and many interviewees emphasised the importance of providing objective information. Concrete measures taken so far were mainly providing information. In particular, information-disseminating through Internet and printed publications were used. In addition, it was clear that these types of communication were more positively practised in European companies.

When asked about 'opinions on bioethics in biotechnological companies', some companies expressed specific concerns and the necessity of taking measures to deal with the issues. Some pointed out the importance of the international framework. In addition, it was clear that there were fears of overreaction by the public about bioethical issues. This also came out in interviews: some expressed the fears that the media amplified the issues or provoked discussions unnecessarily.

The comments in questionnaires could be separated into seven groups, as below, with some illustrative examples of open comments (number of companies indicated):

- Have concerns about the issues (6): 'I don't think many companies take this issue seriously, and they do so at their own peril.'
- Some measures should be taken about the issues (2): 'Wrong goals or people wishing to misuse biotechnology should be prevented through legal intervention.'
- International framework should be needed for the issues (2): 'This should be organized on an international level.'
- It is needed to consider each case (1): 'Consider each case on its merits.'
- Fuss about bioethics troubles us (4): 'Too much emphasis on short-term results.'

44 per cent had communication programmes including consumer education about biotechnology

- No problem because it is enough discussed (2): 'Our experience is that standards of bioethics are higher in companies than can be enforced in universities.'
- Think that it is not our problem for the time being (3): 'In our field of application (Environment) there are other ethical issues.'

DISCUSSION AND CONCLUSIONS

The authors found that more companies said they expected to have bioethical concerns in the future and few admitted to problems in the past in the survey. In contrast in the interviews most people discussed some problems or mistakes in the past, which was attributed to greater trust in face to face communications rather than in written communications. This has some methodological implications for future research, suggesting that a more accurate reflection of actual company policy may be obtained by the interview method rather than the written survey method. The poor response rate was also a drawback of the written survey approach.

The results of both methods indicate clearly that in companies involved in biotechnology, bioethical problems do occur. Few companies do not feel any pressure from outside the company to respond to bioethical issues. They respond in different ways and their practices for dealing with these issues are quite diverse. These efforts, for instance establishment of systems such as ethics committees and education for employees, seem to be developed more in large companies.

Many of the people surveyed and interviewed who are concerned with biotechnology companies think it is not possible to solve bioethical problems by the efforts of only one company and recognise the necessity of communication with the public, and education about biotechnology and bioethics. In addition since only 11 per cent of companies answered that they had codes of ethics or guidelines related to bioethics, it is clear

that other reference points, such as laws and or even external bioethics committees (eg the Science and Ethical Advisory Group of F. Hoffman-La Roche Ltd⁷), are needed when companies face bioethical issues. Also only 11 per cent said they had a policy or policy statement on the issues concerned, and 5 per cent said they had general codes of ethics or codes of conduct not especially about bioethics. Some large companies had responsible persons for bioethics, but it is an open question whether the response of a company should be focused on nominating particular persons, 8 or rather on educating all employees. Given the low level of public trust in companies as a source of information about biotechnology,⁹ they may use strategies to follow guidelines of national or international organisations.¹⁰

There have been a range of international organisations, from United Nations bodies, to academic societies, to conference declarations, which imply that companies have moral obligations. One of these is the Human Genome Organization (HUGO) whose Ethics Committee Statement on Benefit Sharing¹¹ suggests that companies using human DNA should allocate 1–3 per cent to humanitarian purposes.

Only one company however mentioned the UN Global Compact,12 which may be because most companies do not think it is related to bioethical issues. (The UN Global Compact commits companies to work for a sustainable future and to consider their environmental and social responsibilities. The agreement could be followed by many non-signatory companies as the best practice model for industry.) If so this means either people are not aware of the detailed contents and commitments of the UN Global Compact, or they believed the questions related only to specific bioethical issues related to biotechnology. Despite frequent referrals to the industry organisation positions of BIO and EuropaBio, it is not clear how well respondents knew the details of the actual

Some hesitance to admit past bioethics problems

The interview method may be more accurate than written surveys

Many large companies have ethics committees and employee education

BIO and EuropaBio bioethics statements were cited

positions. A Danish study has suggested that biotechnology regulation changes the rate and direction of new biotechnology development, and may contribute to public acceptance of biotechnology.¹³

The respondents also have concerns about biased or distorted information because of media overreaction and they feel it is important to provide objective information. There are often very critical articles written about multinational companies, some of which have become focal points of attack, 14 for what is really a broader criticism of the application of market economic systems to biotechnology.¹⁵ There has also been the use of trendy words to promote the image of companies, such as 'genohype'. 16 Some interviewees said there are social pressures related to these issues from external bodies. In addition, differences in cultural and ethical values among nations or regions were mentioned as a point that should be taken into account in doing business. The relationship between public relations and ethics is another area for future research. Further research to overlook the present situation of bioethics in biotechnology-related companies must be conducted to better bridge public understanding with sound progress of commercial biotechnology.

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Companies need to take

account of differences in

values between nations

cultural and ethical

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