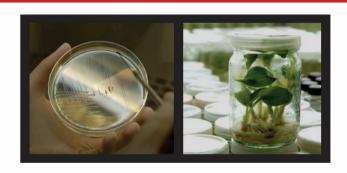


Thailand Updated Status and Perspective on Research and Development of Modern Biotechnology and Biosafety Regulation

WHITE PAPER



Third Edition

prepared by **Technical Biosafety Committee (TBC)**

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Technical Biosafety Committee (TBC)

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Updated Status and Perspective of Thailand on Research and Development of Modern Biotechnology and Biosafety Regulation

Third Edition

Technical Biosafety Committee (TBC)

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FOREWORD

It is estimated that the world's population will reach 9 billion people by 2050. Despite the enormous advances made in increasing agricultural productivity over the last 25 years, more than 800 million people in the world remain undernourished. Changing demands of diets, global warming, growing populations, and, recently, the need for alternative energy from crops to replace fossil-based fuel are putting tremendous pressures on the ability of countries around the world to feed their citizens. In addition, current energy supplies also fail to meet the daily needs of the world's poor. Over one billion people worldwide lack access to electricity in their homes and continue to rely on wood, straw, dung and other traditional biomass fuels to meet their energy needs.

Modern biotechnology has the potential to address these global concerns about food, energy, environment and health. It can help improve both the quantity and quality of the world's food supply. For example, staple crops with enhanced nutritional values or with desirable traits such as drought resistance could have a significant impact on developing nations.

It is vital that developing countries such as Thailand have access and the ability to use biotechnology to address these urgent development needs. Thailand recognizes the fundamental role that biotechnology can play in of improving the quality of life for the rural poor as well as providing a much needed source of revenue.

The challenges facing biotechnology in the years ahead are not just scientific and technological but also relate to matters of public policy and public perception. Thailand has put much effort into ensuring that biotechnology is practiced within the Kingdom in a sustainable and safe manner. Through consultations with international partners, it has put in place the required infrastructure and capacity to support a sound, science-based policy and regulatory framework.

Decisions made by the relevant authorities concerning the use of modern biotechnology are being taken with full public participation and scrutiny. The purpose of this paper is to provide the reader with a perspective on key issues and information relating to Thailand's readiness. We hope that this paper will be a valuable contribution to the discussion on the fundamental role that modern biotechnology will play in the years ahead.

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Chairman of Technical Biosafety Committee (TBC)

INTRODUCTION

The role of agricultural sector has grown of greater importance and agro-industrial development is increasingly recognized as an important engine for economic growth. For many years Thailand has successfully utilized innovations in agricultural research and technology to develop a vibrant agricultural sector. In order to maintain this drive it is necessary for Thailand to continue support the development and capacity building in research and development of genetically modified organisms and their products to ensure self-reliance, effectiveness and competitiveness while taking into account the safety of consumers.

Research and development in genetically modified organisms is not new to Thailand. In 1992, the country was one of the first in the region to adopt a national biosafety guidelines for both laboratory work and field testing and planned release. The guidelines were initiated by National Center for Genetic Engineering and Biotechnology (BIOTEC), National ScienceandTechnologyDevelopmentAgency(NSTDA) under Ministry of Science, Technology and Energy (MOST).

Subsequently in 1993, the National Biosafety Committee (NBC) was established while BIOTEC served as the coordinating body and secretariat. Later on, many Institutional Biosafety Committees (IBCs) were established by various research and academic institutes throughout Thailand. NBC has been the host for all technical biosafety matters as technical support to various government authorities in decision—making concerning the safety of genetically modified organisms. This committee functions as technical

advisory group and risk assessment body, working in coordination with relevant government agencies in the approval process.

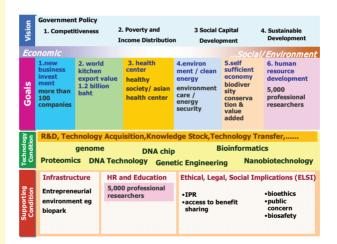
The first introduction and field testing of genetically modified organism in Thailand was with Flavr Savr tomato. The Department of Agriculture, Ministry of Agriculture and Cooperatives (MOAC) with technical recommendation from NBC, granted permission for the field trial of Flavr Savr tomato in 1994. Additional field trial were also permitted for other goods such as genetically modified cotton with toxin gene from *Bacillus thuringenesis* (Bt) in 1995, Bt cotton in 1996 and Bt corn in 1997 etc. However, due to mounting pressure from NGOs, the Cabinet on April 3, 2001 decided to suspend all field-testing of transgenic plants in Thailand. Therefore, all trials conducted for research purposes can only implemented in laboratories or greenhouses setting.

With the establishment of the new Ministry of Natural Resources and Environment (MONRE) in 2002, all biosafety issues related to Cartagena Protocol were then transferred to MONRE which serves as an official national focal point. On February 8th 2006, Thailand became the 128th member country of the Cartegena Protocol on Biosafety. As the central mediator for the Protocol, the Office of The Natural Resources and Environmental Policy and Planning (ONEP) cooperated with related organizations such as the Department of Agriculture, Department of Fisheries, Department of Development, FDA, BIOTEC, Livestock academic institutes and private establishments, in developing a system of biosafety protocols. The system consists of an administrative council and committee to oversee and liaise between parties on important issues, as well as establish and develop the national framework regarding biosafety in Thailand.

National Biotechnology and Biosafety Policy

1. Thailand's National Biotechnology Policy and Biosafety Policy

Thai government foresees the potential of biotechnology towards the development of the country. The government provides the supports to the business and society. The $1^{\rm st}$ national biotechnology policy framework focused on utilizing biotechnology for the prosperity of the business, the self-sufficient economy, and the wellness of society. The strength of the nation has been announced as the six national goals.



One important goal is to promote Thailand as the kitchen of the world. To keep the position as the world food exporter, Thailand needs to find solutions to produce agricultural products that meet the demands and environmental changes. Genetically engineering technology is one approach. The National Biotechnology Policy Committee launched the National Biosafety Policy that focuses on public awareness and education, risk assessment and management, and capacity building. On November 7th, 2007, Thailand's biosafety policy has been accepted by the Compliance Committee on Biosafety, Office of Natural Resources and Environmental Policy and Planning.

To date, the society has some debatable issues between benefit and risk of transgenic organisms especially in the agricultural industry. In addition to the biosafety policy, the government launched the strategy called "Freedom of Choice". It means that public should be educated and able to choose the best choice suited their needs; either GM or non GM.

To strengthen the R&D capability, in December 25, 2007 the Cabinet approved the conducting of field trial within government research station with a number of conditions. Researchers have to define planting area and type of crop, to propose risk management, to provide information on possible effects on environment and human health, as well as to gather public opinion. To alleviate the task, the Technical Biosafety Committee (TBC) under BIOTEC prepared a specific guideline called "Models for field trial of genetically modified papaya, tomato, pineapple, and corn". This guideline provides public assurance on the release of these 4 targeted genetically modified crops in Thailand. Table 1 shows the chronology of GMOs related events in Thailand.

Principal Concepts of the draft National Biosafety Policy

- Public Awareness, Education and Participation: Requiring the involvement of affected parties in policy-level decision-making on the suitability, advantages and risks of the technology in question.
- Sustainability: Sustainable bioresource management must be taken into account the sustainability of the ecology, preservation of species and genetic pool.
- Risk Assessment and Management: Risk acceptability will be assessed and managed on a case-by-case basis according to the Guidelines on Biosafety which will be based on scientific grounds first and foremost.
- Risk Characterization: Characterizing risks for the management and control of GM materials will depend on the outcome of the risk assessment.
- 5. Risk Communication: Risk communication will be based on basic scientific concepts simplified for the public, in order to lessen the anxiety of affected parties, to increase public trust in research results, as well as to curb possible panic from sensitive or contradictory information.
- 6. Precautionary Principle: Care will be taken to avoid unnecessary damage from the lack of reliable scientific data on possible effects of GM materials on the conservation and utilization of biodiversity, environment, and health care.
- 7. Freedom of Choice: In utilizing GM materials for everyone, including consumers, entrepreneurs, academics, farmers, as well as the concerned general public, the government must provide transparent, accurate and up-to-date data for the public in order to encourage inform decision-making by the public.
- **8. Capacity Building:** National capacity building on Biosafety and modern biotechnology to increase efficieny in technology development and safety regulation will be developed.

Table 1: Chronology of GMOs-related Events in Thailand

Year	Activities
1992	Initiation of the National Biosafety Guidelines
1994	First application for field test of importing transgenic plant for seed production (Calgene's Flavr Savr tomato)
1994	A list of 40 prohibited transgenic plants added to the 1964 Plant Quarantine Act
1996	Complete the first Biosafety Guidelines for laboratory and field test
2000	Preparing of GM food labeling by Thailand Food and Drug Administration (FDA)
2000	Revision of the 89 transgenic plants with exception for GM corn and soy bean for processed food, feed, and industrial utilization
2001	A controversial resolution by the cabinet to stop Department of Agriculture's large scale field trials
2002	Ministry of Public Health adopts GM food labeling law
2005	Approval of the roadmap for R&D of transgenic plants by the National Biotechnology Committee
2007	Approval of an extension of GM crops within government experimental stations by the cabinet
2008	Approval of the draft of National Biosafety Act by the cabinet

2. R&D Roadmap

The Thailand GMO roadmap was acknowledged and endorsed by the Thailand National Biotechnology Policy Committee. The roadmap outlines Thailand's strategy for building R&D capabilities from research and development to commercialization. Following is the

summary of the roadmap:

1. To raise human resource capabilities in technology development to international standard levels. The roadmap emphasizes the development of transformation technology and expression systems for local crops, for use in the genetic modification.



2. Traits improvement should be targeted for plants that have significant impact on the Thai economy, society and environment.



3. To strengthen Biosafety assessment capability as well as regulatory controls of open systems and field trials, to build up public confidence in the regulatory agencies' ability to control and monitor open field trials of geneticaly modified plants. The roadmap also emphasies the development of new technologies to support biosafety assessment.

4. Promote public understanding and participation in the decision process, by disseminating accurate information to the public. This will allow the public to make rational judgments on whether to accept or reject products derived from new technologies.



5. IBC is an important regulatory body at the institutional level. BIOTEC is the national coordinator of these 35 IBCs. One of the important roles of BIOTEC is to strengthen the technical capacity of these IBCs through training and dissemination of information. Moreover, BIOTEC also organizes an annual IBC conference as an arena for IBCs to exchange and share their experience.

For the strategic GMO roadmap to be successful, Thailand needs to have a clear policy on field trials, management systems for intellectual property and natural resources, human resource development and infrastructure to support R&D in modern biotechnology and biosafety.

Research and Development in Modern Biotechnology

Research and development on genetically modified organisms is widely conducted in a number of government institutions and universities. Thailand biosafety research network has been established to expedite the research activities related to the transgenic technology.

In the agricultural industry, a number of plants

are ready for biosafety testing. The ringspot virus-PRSV resistant papaya, retardant-ripened papaya, vein-banding mottle virus resistant chili, and color-changed orchid are good examples.





The use of genetically modified microorganisms for enzyme industry is another good example. To date, Thailand developed technological capability called metagenomics which help expedite the process of screening genetic material

directly from environment. The developed transgenic enzymes have high potential to be used widely in animal feed industry, pulp & paper industry, and biorefinery. The lignocellulolytic enzymes is also developed in laboratory scale to converse agricultural waste to value added products.

In addition to the agricultural industry, genetically modified organisms have also been developed for medical use. The examples include growth hormone and vaccine against pandemic influenza.





Infrastructure

To date, there are several agencies working together to facilitate, assist, and monitoring activities related to transgenic organisms. Biosafety structure includes the national focal point for Cartagena Protocol, competent national authorities, and institutional biosafety.

1. National Focal Point for Cartagena Protocol

Ministry of National Resources and Environment (MONRE) has served as an official national focal point for all biosafety issues related to Cartagena Protocol since 2002. In February 8th 2006, Thailand became the 128th member country of the Cartagena Protocol on Biosafety. Under MONRE umbrella, the Office of the Natural Resources and Environmental Policy and Planning (ONEP) was assigned to be the central mediator of the cooperation among competent national authorities.

2. Competent National Authorities

Thai government assigned several agencies to assist the development of activities utilizing the genetically modified technology. These agencies are responsible for field trial and environmental release in the dependable areas.

- Ministry of Agriculture and Cooperatives
 - o Department of Agriculture: Responsible for the registration and approval of utilizing genetically modified crops, testing in a controlled environment, intentional leaks into the environment within the permitted zone for agricultural production and research.
 - o Department of Livestock Development, Department of Fisheries: Responsible for all permits for the usage of genetically modified animals, aquatic

animals and their subsequent products under controlled conditions.

• Ministry of Public Health

o FDA: Responsible for the registration and approval of genetically modified products created for human consumption.

Ministry of Science and Technology

o BIOTEC: Responsible for the registration and approval of genetically modified plants, animals and microorganisms under controlled conditions, for further use in development and non-profit research.

• Ministry of Natural Resources and Environment

o Department of Forestry, Department of National Parks, Pollution Control Department of Marine and Coastal Resources: Responsible for the approval of genetically modified plants, animals, or microorganisms intentionally released into the environment outside of the permitted zone.

• Ministry of Industry

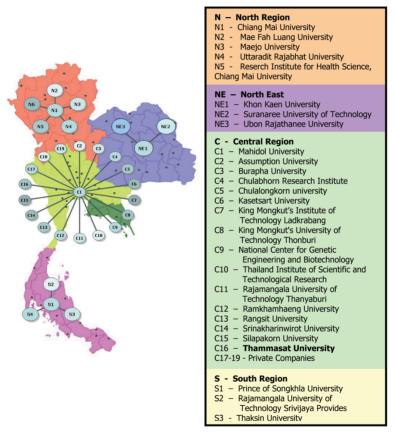
o Department of Industrial Works: Responsible for the registration of genetically modified microorganisms under controlled conditions for industrial production.

• Ministry of Commerce

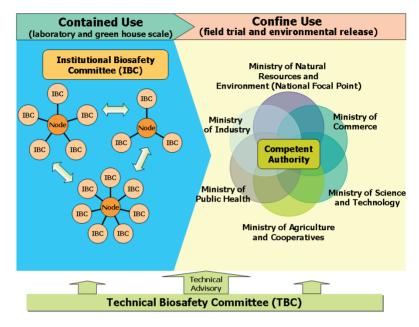
o Department of Foreign Trade: Responsible for the approval of imports or exports involving genetically modified organisms or products.

3. Institutional Biosafety Committee (IBC)

To assist the safety research practically as shown in the biosafety guideline, the Institutional Biosafety Committee (IBC) has been established within academic and research institutes. The main role of IBC is to supervise the internal research in laboratory and green house. Examples of issues include ordering, production, transportation, and release of GM material to the environment. Currently, there are 35 IBCs scattering in 4 main parts of Thailand as shown in figure.



IBC network



Infrastructures of Biosafety in Thailand

Biosafety Related Legislation

1. Existing Biosafety Relapted Laws

Currently the Office of the Natural Resources and Environmental Policy and Planning (ONEP) under Ministry of Natural Resource and Environment (MONRE) is finalizing the National Biosafety Act. The act consists of 108 articles in 10 sections with a framework to regulate and, meanwhile, to promote the use of genetically modified technology. During this time, the following related acts are put in place.

 Plant Quarantine Act B.E. 2507 (1964; amendment 2010)

This act prohibits 33 species, 51 genera and 1 family to be imported into the Kingdom except for research and development granted by the Director General of the Department of Agriculture (DOA) in compliance with DOA biosafety guidelines on importation of prohibited material. If the transgenic plants or plant propagated materials are planned for human consumption, information on food biosafety assessment from Subcommittee on Food Biosafety is required.

• Plant Variety Protection B.E. 2542 (1999)

New plant species and the holder of the plant variety right are protected under this act. A transgenic plant which is registered under this Act shall be assessed for potential risks.

 Pathogens and Animal Toxin Act (No.2) B.E. 2544 (2001)

This act prohibits the importation, exportation, or transit of pathogens or animal toxins without a permission of the Director General of the Medical Sciences Department, Ministry of Public Health.

• Food Act B.E. 2522 (1979)

Ministerial notification No. 251 under this act enforces the labeling of food containing the 5% threshold level of DNA or protein from GM soybean, GM corn, and their products

	Importation	R&D	Field Test	Commercialization
Plant	Plant Quarantine Act	Biosafety guidelines Plant Quarantine Act	Biosafety guidelines Plant Quarantine Act	Food Act
Microbe	Pathogens and Animal Toxins Act	Biosafety guidelines	Biosafety guidelines	Microbial Industrial Guidelines

Existing Legislation and Guidelines Realted to GMOs

2. Draft National Biosafety Act

The decision of the Thai Government to become a Party to the Cartagena Protocol on Biosafety addresses biosafety issues and points to the need to put in place a legislative framework for the entire country. Obligations by the Party under the Cartagena Protocol on Biosafety were synthesized in order to identify components of the country's biosafety laws that should be included so that the Protocol can be effectively implemented for the benefit of the country. The drafting Committee has approved the draft Biosafety Act (issued on April 2007), consisting of 108 Articles in 10 sections. Such a framework would define how Thailand can regulate and promote modern biotechnology at a pace faster than in the past. The cabinet approved the draft of National Biosafety Act in 22 January 2008 and is under consideration by Office of the Council of State of Thailand.

Draft Biosafety Act

Rational (according to latest draft April 2007)

The current progress and development of modern biotechnology in using living modified organisms is very promising to several areas and perspectives namely agriculture and human health. Thailand recognizes its significant importance to development and is also aware of safety concerns to the environment, biodiversity and human health. The need to promulgate a legislation to regulate the use of living modified organisms either imported or produced within the country is of crucial concerns. The act will assist all stakeholders to have necessary and appropriate tools and procedures to handle living modified organisms in compliance with international community.

- The draft biosafety act (April 2007) currently consists of 9 chapters enumerating 108 Articles covering all substantial issues;
 - General provisions (Art 1-18) 0
 - Operational provisions (Art 19-63)
 - Supportive provisions (Art 64-108)
- The draft biosafety act contains;
 - Advanced inform consent
 - 0 Case-by-case and step-by-step approach
 - Risk-based regulation 0
 - Precautionary principle 0
 - Socio-economic consideration
 - Public participation and opinion
 - Science-based basis
 - Joint liability and redress

3. Biosafety Guidelines

In addition to the law and legislation, the Technical Biosafety Committee (TBC) under Ministry of Science and Technology developed three biosafety guidelines for the safety of research & development, field testing, and commercialization.

- Biosafety Guidelines for Research and Development: The guidelines have been the first discipline in biosafety and used by researchers and developers who involve in genetic engineering since 1992.
- Food Biosafety Guidelines: based on the concepts used by the Codex Alimentarius Commission, namely: Principles for the Risk Analysis of Foods derived from Modern Biotechnology, Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms.
- Biosafety Guidelines for Industrial Application of Genetically Modified Microorganisms: provide an important framework for entrepreneurs to utilize genetically modified microorganisms in all industrial production.



Risk Assessment and Risk Management

1. Risk Assessment

Thailand biosafety evaluation and risk assessment of genetically modified organisms and their

products are to be carried out on scientifically sound and case-by-case basis particularly in transparent manner procedural basis. Relevant agencies are requesed to



jointly conduct these tasks using the same measures for imported, domestically produced and exported products. Food and environmental risk assessment require competent and technical-specific, experienced experts. Thailand is consequently building capacity for food and environment risk assessors. A training course and curriculum for regional experts in the country is developed to screen a number of qualified personnel to be listed in a roster of biosafety country experts serving for risk assessment process in the near future.

2. Risk Management

Based on the Cabinet's decision on April 3, 2001, Thailand does not allow importation and production of any transgenic plants for commercial purposes and field trials except for: (1) processed food; and (2) imports or sales of soybeans and corn for feed use, human consumption, and industrial use. Furthermore, all trials conducted for research purposes must be contained in laboratories or greenhouses.

On December 25, 2007, the Cabinet has approved the Ministry of Agriculture and Cooperatives to prepare for an extension of GM crops within government experimental stations. The plan requires



clear definitions of the planting area, the crop, control methods studies on the effects on the environment and health in nearby locales, as well as gathers public opinion and other

interested parties according to Article 67 of the Constitution of Thailand. The study should be integrative and cooperative to reach a mutual agreement before submitting to the Cabinet for each area.

In case of risk assessment of field trial testing, Technical Biosafety Committee under BIOTEC had prepared a specific guideline called "Models for field trial of genetically modified papaya, tomato, pineapple and corn". The guideline was developed from the Biosafety Guidelines for Work Related to Modern Biotechnology or Genetic Engineering in order to provide public assurance on the released filed trials of 4 targeted genetically modified crops in Thailand.

Public Awareness and Participation

1. Biosafety Education

Article 22 of the Cartagena Protocol on Biosafety requires Parties to cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology. After the third meeting of the academic institutions and

organizations involved in biosafety education and training, biosafety has become part of a curriculum of agricultural biotechnology MSc and PhD program at Kasetsart University of 3 units credit at Kasetsart University.

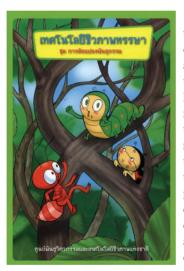


2. Public Awareness and Education



Realizing the importance of public participation is a strong driving force for progress of modern biotechnology and the public awareness in the technology is a foundation of efficient public participation. Public and private sectors in Thailand have been in cooperation to implement various activity programmes to promote public awareness in science and regulation of genetically modified

organisms since 2001. In response to the fact that there are different stakeholders in the public, public awareness programmes in Thailand are strategically planned and implemented in according to interest and concerns of each group of stakeholders. Mainly, the stakeholders are categorized, based on their interest and concerns, into four groups of 1) students and educators, 2) farmers and agricultural extension officers, 3) food producers and 4) general consumers. Awareness in modern biotechnology is then raised and strengthened in each group through different education and communication activities designed to accommodate concerns and interests of each group.



In general, education the and communication activities are to provide information through channels of public seminar and mass media communication such as newspaper, newsletters, radio and television. In addition to information on examples of benefit and risk of adopting the technology, basic knowledge about DNA, development of genetically modified organisms and biosafety

are also provided to the public. This is in order to move forward to develop a knowledge based public participation where the public can compromise concerns with the scientific facts. Public education on complicate science has then been facilitated by translating biotechnology and biosafety information into various forms of nice-and-easy articles and educational materials for broadcasting and publication which includes cartoon books for children. Educational tools for learning about DNA, gene transformation, and biosafety were also specially designed and produced to enhance the learning atmosphere in a learn-and-play manner.

As a number of personnel are needed to provide information and knowledge to the public at large, the knowledge multiplier training programme has been introduced to generate "technology communicators" in local communities in all four parts of Thailand. Farmers, agricultural extension officers, high school teachers and general consumers who have potential in communication were trained in a short course on modern biotechnology and biosafety.

Currently, more than 30 trained technology communicators are serving as an information center in their own community and a linker between local public and academic institutions for update information. The technology communicators also serve as "knowledge multiplier" distributing knowledge to larger scale of public through meetings and seminars that they organize with support from the government. Through these public meetings and seminars, thousands of people have had chance to interactively update information on the technology, discuss their needs and concerns and translate them into sound recommendation to the authorities and the rest of the society. Moreover, those participated in the meetings and seminars can be the next knowledge multiplier delivering information knowledge they gained to the others in their way of life.

To facilitate the public education in genetic modification and biosafety, three educational media were developed, the cell-DNA-genetic engineering model,

the particle bombardment toy, and the biosafety model. Using the cell-DNA-genetic engineering model. instructors demonstrate cell structure and organelles. A string of DNA can be pulled from nucleus to show DNA structure and how DNA could be cleaved and joined. The Cell-DNA-Genetic Engineering particle bombardment toy allows class to try for



Model

themselves, as they were in real laboratory; on how the gene is introduced into cells and why selectable marker gene is necessary. And, the biosafety model was designed to demonstrate the tightly control quality and safety assessment process of transformed plants according to regulations and requirements.

Particle Bombardment Toy



Biosafety Model



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