White Paper

The Precautionary Principle & Animal Agriculture

Information synthesized from the Opening and Closing General Sessions of the National Institute for Animal Agriculture's Annual Conference, "The Precautionary Principle: How Animal Agriculture Will Thrive," conducted April 1-2, 2014, in Omaha, Neb. Full presentations are available online at *www.animalagriculture.org*

DISCLAIMER: The information provided in this White Paper is strictly the perspectives and opinions of individual speakers and discussions at the 2014 Annual Conference of the National Institute for Animal Agriculture.

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ABSTRACT

The Precautionary Principle, an outgrowth of increased environmentalist awareness since the 1970s, is a principle for making decisions under conditions of scientific uncertainty. Comprised of four central components, the principle was designed to 1) initiate preventive action as a response to scientific uncertainty; 2) shift the burden of proof to the proponents of a potentially harmful activity; 3) explore alternative means to achieve the same goal; and 4) involve stakeholders in the decision-making process.[1]

Many national governments have accepted the Precautionary Principle as a basis for policymaking. While the principle is not mentioned by name, the Precautionary Principle is at the basis of some U.S. food and drug and environmental legislation and regulatory decisions.

The actual content of the Precautionary Principle and the practical implications of its implementation in policy issues are controversial. While some individuals and groups maintain that the Precautionary Principle's "better safe than sorry" approach and placing the burden of proof on the proponents of a proposed activity are in the best interest of society, others contend that the principle has become a politically charged approach that can lead to innovation being blocked.

With the world's population projected to reach more than 9 billion by 2050, the challenge of feeding a growing global population is daunting. This situation stirs the need for those in animal agriculture to investigate the Precautionary Principle and its impact on how innovative and competitive U.S. agriculture will be in the global marketplace.

The National Institute for Animal Agriculture—a non-profit, membership-driven organization that unites the aquatic livestock, beef, dairy, equine, goat, poultry, sheep and swine industries—focused its 2014 Annual Conference on "The Precautionary Principle: How Animal Agriculture Will Thrive." This paper reflects information provided by the Opening and Closing General Session speakers at the event.

NIAA is dedicated to providing programs that advance animal agriculture; work toward the eradication of diseases that pose risk to the health of animals, wildlife and humans; promote the efficient production of a safe and wholesome food supply for our nation and abroad; and promote best practices in environmental stewardship and animal health and well-being.

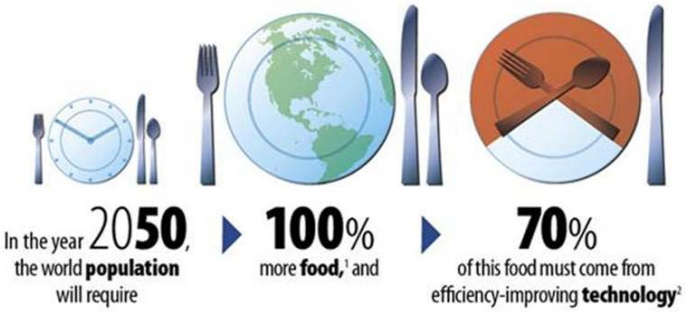
PRESENTATION HIGHLIGHTS

The Precautionary Principle and Agriculture

Innovative ideas, technologies and practices are required if the world's growing population, which is expected to reach 9 billion people by 2050, is going to be fed. By the middle of the 21st Century, food production must double to meet demand—and this challenge must be met using less land and less water than previous generations used to feed fewer than 2 billion people.[2] Worded another way, over the next 50 years, the world's farmers and ranchers will be called upon to produce more food than has been produced in the past 10,000 years combined, and to do so in environmentally sustainable ways.[3]

Producing an adequate supply of food for a growing world has its challenges. One of those challenges is climate change. Data shows that global temperatures are rising, and food production is—and will continue to be—impacted by this rise in global temperatures.[4]

Action taken in the next 10 years will shape the earth and humanity for the next 100 years.[5] In 2002, the Food and Agriculture Organization of the United Nations noted that 70 percent of the world's additional food needs can be produced only with new and existing agricultural technologies.[6]



Herein lies another challenge, as a key factor that has the potential to hinder food production innovations—the very ones needed to feed a growing hungry world—is the Precautionary Principle. While the Precautionary Principle has the same roots as the precautionary approach, the Precautionary Principle and a precautionary approach are not the same.[7]

A precautionary approach is when regulators, not knowing in advance the full extent of risk associated with an innovation, are cautious and seek more information about the product. Regulators request that the developer furnish more information or data that details potential risks, thus allowing the regulator to address areas of risk that are of legitimate concern. The end goal is for regulators to be armed with relevant information so they can make the best possible decision based on science and facts.[8]

Whereas the precautionary approach is used as the basis to ask questions and examine a situation more closely prior to making a decision, the Precautionary Principle attempts to use the adage "better safe than sorry" as the defining mechanism for formulating and reshaping policy and framing the

examination of risk. One challenge of the Precautionary Principle when using it as the basis for setting policy is that there is no single, generally agreed-to definition.[9]

While the World English Dictionary defines "precautionary principle" as "the precept that an action should not be taken if the consequences are uncertain and potentially dangerous,"[10] a popular and often quoted definition[11] is the Wingspread Statement on the Precautionary Principle that was developed by a group of environmentalists in 1998: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically. In this context, the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the precautionary principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action."[12]

Several challenges arise when the Wingspread Statement on the Precautionary Principle is used as a basis for formulating policy:[13]

- The perception of what constitutes a threat of harm to humans or the environment is subject to personal interpretation.
- It does not specify who or what defines the potential risk to human health and the environment.
- If this version of the Precautionary Principle was applied literally, no activity that raises threats of harm to human health or the environment should proceed until proven safe—a positive that could be a barrier to any action that changes the existing condition.
- It is difficult—if not impossible—to meet the burden of proof.
- The "must be open, informed and democratic and must include potentially affected parties" opens the door to extremists, individuals with an agenda and individuals with opinions but with no expertise or knowledge of the subject.
- The principle does not call for an evaluation of the risk that comes from doing nothing.

The Precautionary Principle could be used to prevent any new technology or product from being utilized if a person perceives that it might cause harm—and this belief takes hold without any consideration being given to the risks associated with the technology or product not being adopted.[14] In addition, "When selectively applied to politically disfavored technologies and conduct, the Precautionary Principle is a barrier to technological development and economic growth."[15]

The Precautionary Principle is used in Europe, with risk not defined by science or data but by those in charge.[16]

While risk assessment is important, it can be corrupted by people and groups who exaggerate risks to instill fear. The introduction of innovative products face competing interests:[17]

Science-based Regulation	Opposition
Transparency	Exploit transparency/Freedom of Information
Risk assessment	Dispute science/Risk assessment
Risk communication	Create fear and anxiety
Risk mitigation	Exaggerate risk
Enforcement	Litigation

The Precautionary Principle: A Case Study[18]

AquAdvantage Salmon is a case study of how taking caution to an extreme can hinder implementation of food technologies that could help feed a growing world population.

AquAdvantage Salmon, a product developed by AquaBounty Technologies, is a genetically modified variety of Atlantic salmon that has a single gene from a Chinook salmon spliced into its genome. The amount of DNA represented by the AquAdvantage gene construct in the salmon genome is 0.0001% or 1/1,000,000 of the total DNA. When compared with standard salmon, AquAdvantage Salmon reach 100 grams in 138 fewer days, are ready to market in half the time, consume 20 percent less feed and have a 5 percent better nitrogen retention.

AquAdvantage Salmon has been under regulatory review by the federal government for 19 years, and, as of April 1, 2014, remains unapproved.

The Coordinated Framework for Regulation of Biotechnology, proposed in 1984 by the White House Office of Science and Technology Policy and finalized in 1986, spells out the basic federal policy for regulating the development and introduction of products derived from biotechnology—such as the AquAdvantage Salmon. A key principle of the framework is that genetically engineered organisms would continue to be regulated according to their characteristics and unique features, and not according to their method of production. In other words, if a food product produced through biotechnology is substantially the same as one produced by a more conventional means, this food is subject to no additional or no different regulatory processes. The framework also maintains that new biotechnology products are regulated under existing federal statutory authorities and regulations. An interesting note is that, since 1986, the federal government has approved only one genetically engineered animal, a goat that produces human anti-thrombin A in its milk.[19]

AquAdvantage Salmon has met numerous challenges during the federal regulations review process. While some people expressed legitimate viewpoints, other individuals and groups simply do not like animal agriculture and brought up social and economic concerns that were not based on science. Citing concerns over food safety, crossbreeding and environmental damage, environmental groups and other interests lobbied heavily against the approval of the AquAdvantage Salmon. Feeling threatened, the Alaskan wild-caught Pacific salmon industry sought to halt regulatory approval of the AquAdvantage Salmon, knowing there are few commercial fisheries for the species and that aquaculture facilities provide virtually all the Atlantic salmon on the U.S. market. In fact, the United States imports large quantities of Atlantic Salmon from several countries.

In September 2010, the Food and Drug Administration disclosed its findings that AquAdvantage Salmon is an Atlantic salmon and is as safe to consume as food as any other Atlantic salmon. The FDA also concluded that AquAdvantage Salmon, which will be grown only in a contained environment, represents no significant risk to the environment under conditions of use in application and approval.
It has been two years since the FDA published an environmental assessment and one year since the close of a public comment period. To date, AquBounty Technologies has invested more than $70 million toward approval and has been close to bankruptcy four times.

Support for AquAdvantage Salmon has come from agricultural production states, production associations, academics, animal health companies and scientific associations. Opponents to AquAdvantage Salmon have been, and are, Alaskan fisheries, activist lawyers, organic growers, various non-profit voluntary citizen groups and three states: California, Oregon and Washington.

Technologies can have a Positive Impact[20]
Three regulatory agencies have oversight for biotechnology products under existing legislation:

- U.S. Department of Agriculture (USDA)—Plants and seeds; animal biologics; and meat and poultry.
- Food and Drug Administration (FDA)—Food and feed; human biologics; drugs; genetically engineered animals; and medical devices.
- Environmental Protection Agency (EPA)—Plant pesticides; herbicides; and chemical and microbials.

USDA's approval of biotechnologically advanced seeds led to 1996 being a pivotal year for technology. New small grain traits made their debut and continue to significantly boost production. The technology allowing for the higher yields and meeting the needs of farmers has been approved by the federal government, with all products subject to science-based regulation under existing, product-based statutes. Today, biotech-advanced seeds account for 90 percent of corn and cotton, 90-plus percent of papaya, 93 percent of soybeans and 95 percent of sugar beets produced in the United States.

While the science-based regulatory process in the United States for genetically engineered animals—FDA Guidance for Industry 187—has proven to work and has industry support, political interference in the process does not have support. Political interference can halt innovations, including those that could improve food availability, lower food cost and enhance biomedical research, treatments and production.

Technology is at a crossroads. Factors influencing this crossroads include:

- Animal biotechnology developers are smaller companies and few in number.
- Opponents to technology are well funded.
- Today's regulatory environment is unpredictable.
- Public perception can influence the regulatory decision-making process.
- Trade questions can arise.

Those opposed to technology are intent on changing market conditions through legislation. Opposition is known to attack biotech food, undermine consumer confidence in food safety and challenge value-

chain confidence for genetically engineered ingredients. The opposition-to-technology movement is causing some technology companies to move overseas. China is appealing as it is investing $12 billion in agriculture biotechnology and Brazil is recruiting U.S. researchers.

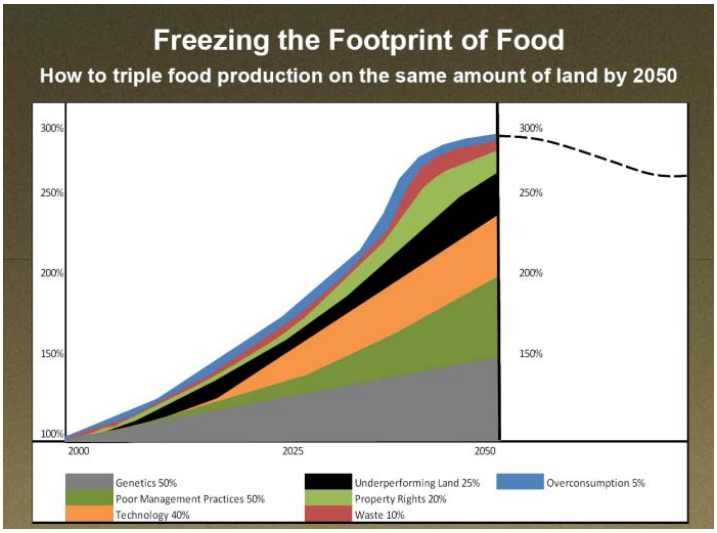
A statement from Dr. Norman Borlaug should be top of mind: "Not one person has suffered negative effects from innovations like GMOs, yet 25,000 people die every day from malnutrition."

Replacing the Precautionary Principle by Focusing on Sustainability[21]

Individuals often focus on certain topics of their own interest rather than looking at the big picture: sustainability.[22]

Persistent Issues	Important Issues
Locally grown	Water use efficiency
GMO crops	Soil erosion
Organic crops	Soil organic carbon
Natural	Land use change – Biodiversity loss

Water use efficiency, soil erosion, soil organic carbon and biodiversity loss are sustainability issues. A graph developed by Jason Clay, Senior Vice President, World Wildlife Fund, illustrates that, if the world is to continue to have wild animals such as tigers, giraffes, etc., the footprint of agriculture must freeze—and this requires innovation if agriculture is expected to produce more on the same or less land.



Key sustainability challenges facing agriculture include:

1. To meet projected demands for food, feed, fiber and fuel from the land, production must be increased by 50 percent to 100 percent in the next four decades.
2. If global production is not increased, U.S. and European production must compensate by increasing even more.
3. If biodiversity and other land-based ecosystem services are to be preserved, the footprint of agriculture must be frozen. (See above graph)

4. Yield—output per area—must more than double in the next 40 years in the United States and Europe.
5. Energy scarcity will drive innovation but will limit expansion of productivity.
6. Water scarcity will limit productivity globally.

Major companies and national and world organizations take sustainability seriously and have developed relationship goals that incorporate sustainability. In addition, while government funding for agricultural research has declined during the past 20 years, private companies are stepping up to the plate and are investing in sustainability research.

Agricultural sustainability, as defined by Field to Market™, is meeting the needs of the present while improving the ability to meet the needs of future generations by 1) increasing agricultural productivity while decreasing environmental impact; 2) improving human health through access to safe, nutritious food and 3) improving social and economic well-being of rural communities.

Key Performance Indicators (KPIs) are items that individuals care about and use to make informed decisions. Sustainable agriculture KPIs should be outcome based, science driven, technology neutral and transparent.

Environmental KPIs specific for agriculture include greenhouse gas emissions, energy use, water use, land use, water quality, nutrient use efficiency and habitat/biodiversity. A 2013 document released by the Food and Agriculture Organization of the United Nations, "Tackling Climate Change Through Livestock: A Global Assessment of Emissions and Mitigation Opportunities," shows livestock greenhouse gas emissions are estimated at 7.1 gigatonnes CO_2e per year, accounting for only 14.5 percent of human-induced greenhouse gas emissions. This 14.5 percent can be reduced, however, through nutrition, manure and husbandry practices such as increasing forage digestibility and digestible forage intakes, increased use of dietary lipids and increasing animal productivity by supplementing with small amounts of concentrate feed.

The Continuous Improvement Framework for Sustainability will enhance the competitiveness of agricultural enterprises while also improving global conditions. This framework for sustainability requires that it first be defined for the enterprise (*see Field to Market definition above*). Goals should be developed starting with a set of aspirational and strategic goals defined by a common vision for each agricultural sector, with operational and tactical goals at the enterprise level to support the strategic goals. The KPIs should be defined and metrics selected so the enterprise benchmark KPI metrics, set goals for each KPI and develop the strategy or strategies to meet those goals. Once this sustainability framework is implemented, results should be measured, assessed and reported and the identified strategy or strategies adapted at prescribed frequencies (usually 5 years) to ensure improved outcomes.

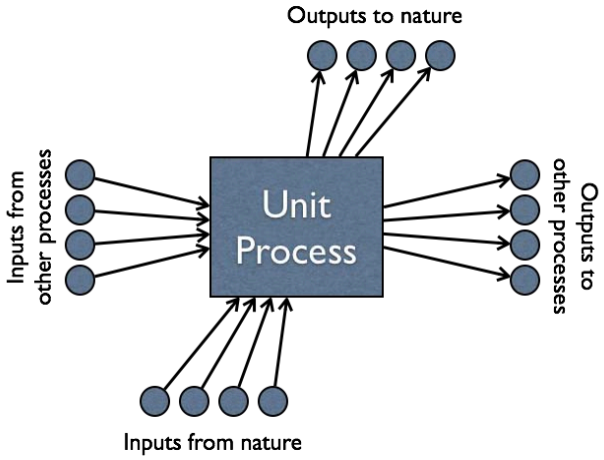
Setting goals for sustainability starts with having a vision and identifying aspirations—what individuals and groups want to achieve—and strategies that can help those aspirations become reality. This high-level goal setting should be the outcome of a collaborative conversation with stakeholders across the supply chain, including organizations that may be perceived critics of the enterprise. The process of exploring collective values can be valuable for identifying common goals. The approach for implementing these common goals should reside with the enterprise, but be transparent. This requires identification of the tactics and operations that make the strategies work. Tactical and operational

goals employed to carry out strategic goals are the domain of enterprise management, creating a transparent approach to make aspirations reality.

Sustainability involves continuous improvement, and, while sustainability isn't complicated, it can be difficult.

U.S. farmers and ranchers have a long history of focusing on sustainable agriculture, with several national agricultural organizations having sustainability initiatives in place. Among the national agricultural organizations are the Innovation Center for U.S. Dairy™, Pork Checkoff®, Beef Checkoff®, American Peanut Council™, U.S. Rice Federation®, USSEC (U.S. Soybean Export Council) and Cotton®/Cotton Incorporated.

Sustainability is at the core of the Center for Agricultural and Rural Sustainability's Life Cycle Analysis (LCA) which looks at supply chain processes. The tool helps companies—those within agriculture and those outside of agriculture—take a cradle-to-grave look at processes: inputs from nature and from other processes and outputs to nature and to other processes.



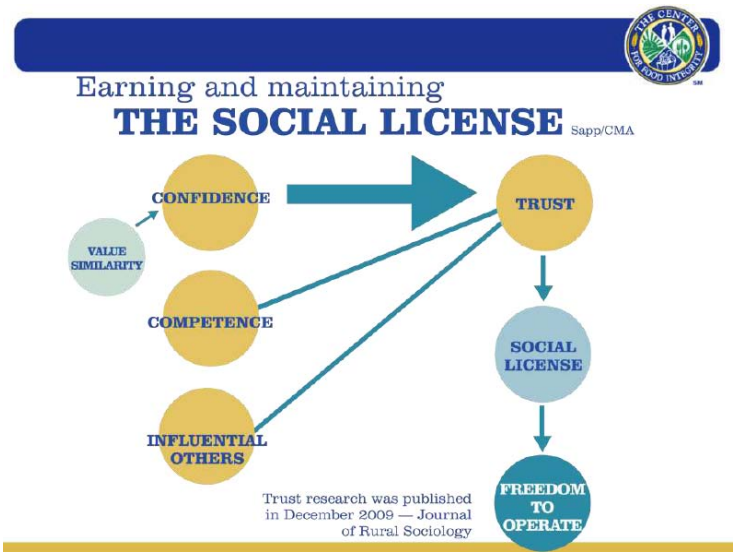
When the big picture is considered and the LCA is applied, sustainability—rather than the Precautionary Principle—should be driving decisions and regulations. By switching the focus to sustainability, short-term decisions that can have negative long-term impact might be avoided.

Increasing Consumer Trust

Meeting demand for food for a hungry world will require not only innovation but that consumers trust agricultural innovations and view them as helpful and not harmful. Whether individuals support the Precautionary Principle or lean their decision-making process more toward sustainability, most consumers and decision-makers today do not know farmers and ranchers and farming and ranching practices. While surveys show that U.S. consumers trust farmers and ranchers, the same surveys indicate that consumers do not trust farming and ranching practices.[23]

The reputation of agriculture and agriculture's social license—the freedom to operate—are at risk.[24]

Earning consumer trust isn't about convincing consumers about the skills and methods farmers and ranchers employ; it's about shared values. Research shows that shared values are three to five times more important in building trust than demonstrating competence.[25]



Today's business climate of skepticism—and overabundance of caution—and helping people become comfortable with innovation can also be addressed by:

- Reducing or eliminating the fear instilled by activists.[26]
- Being transparent.[27]
- Listening to audiences and letting them know their concerns are heard.[28]

CONCLUSION

The continued reliance on a Precautionary Principle approach by government regulators has an impact on the future growth of animal agriculture in the United States, with the consequences of such a policy felt across the agricultural industry.

By using fear of the unknown to stop innovation, those resistant to technology are causing consumers to lose faith in government regulatory systems. Those who are hesitant to utilize technology and chase the elusive “zero risk” are not considering the risk that comes with taking no action at all.

The challenge of finding new innovations in food production without the use of technology is daunting. The expansion of the world population will require a doubling of the food production by 2050. With limited arable land and the increased demand for animal protein, the need for innovation and technology in food production is imperative. As stated by Dr. Walton, meeting demand for food for a hungry world will require not only innovation but that consumers trust agricultural innovations and view them as helpful and not harmful. The use of sustainability KPIs can aid in communicating with government regulatory agencies and consumers on the benefits of technology to the environment. The need to keep government decisions on new food technologies science-based is critical to maintain a healthy planet for a hungry world.

FOOTNOTES

[1]Kriebel et al., "The precautionary principle in environmental science," Environmental Health Perspective, 2001 September: 109(9): 871-6.

[2]Walton, Mark. "The Precautionary Principle — Turning Prejudice into Policy," National Institute for Animal Agriculture 2014 Annual Conference, Omaha, Nebraska, April 1, 2014.

[3]Edwards, David. "Animal Biotechnology: Innovation Stifled by Inaction," National Institute for Animal Agriculture 2014 Annual Conference, Omaha, Nebraska, April 2, 2014. Referencing quote by Jacques Diouf, FAO Director General, 2007.

[4]Walton, Mark.

[5]Matlock, Marty. "Science-Based Metrics for Sustainable Outcomes in Agriculture," National Institute for Animal Agriculture 2014 Annual Conference, Omaha, Nebraska, April 2, 2014.

[6]Edwards, David.

[7,8,9]Walton, Mark.

[10]World English Dictionary, http://dictionary.reference.com/browse/precautionary+principle (Accessed April 10, 2014)

[11]Walton, Mark.

[12]Walton, Mark. Referencing Wingspread Conference on the Precautionary Principle, January 26, 1998.

[13,14]Walton, Mark.

[15]Walton, Mark. Referencing Jonathan Adler's Paper "The Problems with Precaution: A Principle Without Principle."

[16]Walton, Mark.

[17]Stotish, Ronald. "When Precaution Becomes Paralysis," National Institute for Animal Agriculture 2014 Annual Conference, Omaha, Nebraska, April 2, 2014.

[18]Stotish, Ronald.

[19]Stotish, Ronald. Referencing http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009.

[20]Edwards, David.

[21]Matlock, Marty.

[22]Matlock, Marty. Referencing Jason Clay, Senior Vice President, World Wildlife Fund.

[23]Walton, Mark.

[24]Matlock, Marty.

[25]Matlock, Marty. Referencing information provided by the Center for Food Integrity.

[26]Walton, Mark.

[27,28]Edwards, David.

SPEAKERS AND TOPICS *(Listed in the order the presentations were given at the conference)*

"The Precautionary Principle — Turning Prejudice into Policy"—Mark Walton, PhD, *Chief Marketing Officer, Recombinetics*

"When Precaution Becomes Paralysis" — Ronald L. Stotish, PhD, *President and Chief Executive Officer, AquaBounty Technologies*

"Animal Biotechnology: Innovation Stifled by Inaction" — David Edwards, PhD, *Director, Animal Biotechnology*

"Science-Based Metrics for Sustainable Outcomes in Agriculture" — Marty D. Matlock, PhD PE BCEE, *Executive Director, Office for Sustainability; Area Director, Center for Agricultural and Rural Sustainability; Professor, Biological and Agricultural Engineering, University of Arkansas*

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