A CONFERENCE

BRINGING STANDARDS TOGETHER: AN INTERNATIONAL FRAMEWORK

Washington, D.C.
Tuesday, July 18, 1995

Sponsored by the U.S. Consumer Product Safety Commission

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EXECUTIVE SUMMARY

On July 18, 1995, the United States Consumer Product Safety Commission (CPSC) sponsored the international conference, "Bringing Standards Together: An International Framework," with the dual objectives of enhancing consumer protection and increasing international trade. Over 300 attendees from industry, government, academia and consumer organizations joined an extraordinary group of experts from the public and private sectors to share information and help ascertain ways to internationally harmonize consumer product safety standards while maintaining and strengthening consumer product safety.

The conference evolved from the need to ensure that optimal product safety is maintained as an increasing number of consumer products are imported from the growing global marketplace. Making U.S. safety standards compatible with those of our trading partners is becoming the foundation for building strong trade relationships and creating U.S. jobs and effective markets abroad for U.S. products. Therefore, the Toy Manufacturers of America, Inc. and others throughout the international business community urged CPSC to take a leadership role in coordinating efforts to ensure product standard harmonization is recognized as a priority by both the public and private sectors.

Each of the three keynote speakers emphasized the importance of harmonizing U.S. and international product standards to increase U.S. exports and improve product safety around the world.

First, U.S. Trade Representative Mickey Kantor stated that product standards harmonization is a critical link to opening foreign markets, leveling the playing field and breaking down trade barriers. He urged that standards be "harmonized up, and not down," because higher standards mean more safety, greater protection of consumers in the global marketplace and the growth of jobs throughout the world.

Second, the chief executive officer of Toys "R" Us, Michael Goldstein, said more compatible international standards would increase exports and improve product safety standards throughout the world. He argued that uniform quality safety standards worldwide would reduce business expenses substandard or harmful products. He pledged his industry's support to make international safety standards a reality.

Third, Secretary of Commerce Ronald H. Brown stated that with tariffs and quotas falling around the world, product standards are increasingly the most significant barriers to truly free trade. He stressed that standards harmonization could actually become the leading edge of trade arrangements. He recommended a public-private partnership to achieve international harmonization of standards.

Three panels of experts then shared their knowledge and experience on 1) the

history and current status of international trade agreements, standards, and conformity assessment negotiations; 2) government success stories demonstrating different ways to achieve standards harmonization; and 3) private industry's successful experiences and consumer product safety concerns.

Finally, CPSC Chairman Ann Brown closed the conference with a commitment to maintain the levels of consumer product safety that are now taken for granted in the U.S. and to promptly and seriously consider all suggestions and recommendations from the conference on how to promote international harmonization of consumer product safety standards.

Some of the comments and recommendations from speakers, panelists and wrap-up session participants included the following:

1. Increased product standard harmonization would enable the Commission to create alternatives to costly product recalls, reduce regulatory costs of labeling and other means of informing the public about product hazards, more effectively promote educational activities, minimize protracted legal disputes and deal more effectively with the imported harmful products.

2. Effective trade policies designed to expand exports and create jobs must be accomplished by harmonizing up, not down. As a matter of United States policy, safety must not be compromised.

3. The U.S. Government and American industry can, and should, work together to develop a mutually acceptable position tying the benefits of product standard harmonization to economic growth and consumer protection.

4. CPSC first should attempt harmonization on a pilot project basis by developing a compatible standard with Canada, e.g., a toy standard, then attempt to gain acceptance of an effective international toy standard.

5. Federal regulatory agencies, with an interest in product standard harmonization, should cooperate in sharing information, expertise and strategies to contribute to a stronger and more unified comprehensive U.S. harmonization effort.

6. The memorandum of understanding between CPSC and its counterpart, Health Canada, should serve as a model for future bilateral agreements between CPSC and its counterparts in other countries.

7. The establishment of a technical committee on consumer product safety should be considered under the International Organization for Standardization to develop harmonized international standards.

8. CPSC should continue to actively participate in interagency groups developing and implementing U.S. trade agreements. CPSC should become more active in international organizations such as the Organisation for Economic Co-operation and Development to develop responsible policies affecting consumer safety, product standards and international trade harmonization.

9. Where necessary, CPSC should support bilateral negotiations with Europe and other countries to generate mutual recognition agreements covering testing and inspections.

10. CPSC should consider a policy of accepting the integrity of accreditation systems and the results of independent laboratories that support the U.S. market as a means of recognizing the safety of products from abroad.

11. In dealing with foreign regulators, CPSC should adopt positions that promote the lowest cost product certification requirements commensurate with product risk.

12. CPSC should consider the potential for international harmonization of product standards and other regulatory requirements with countries that involve heavy U.S. exports and imports.

OPENING REMARKS

WELCOME AND INTRODUCTIONS

Ann Brown
Chairman
U.S. Consumer Product Safety Commission

Good morning. I'm Ann Brown, Chairman of the U.S. Consumer Product Safety Commission. Welcome to CPSC's conference, "Bringing Standards Together: An International Framework."

Before we begin, I would like to recognize CPSC's two other commissioners, Mary Sheila Gall and Thomas Moore, and to note that we have many distinguished guests here today, including several members of the diplomatic community.

I also would like to thank Senator Slade Gorton of Washington State -- and his hard-working staff -- for making it possible for this conference to be held in such a stately and historic room. This has been the site of many important hearings throughout history, including the Senate Watergate hearings.

This conference is the exciting beginning of CPSC's leadership in harmonizing international product safety standards, enhanced by the level and quality of participation from all of you.

Since I've come to CPSC, we have seen how a cooperative relationship can work between government and industry on a national level. Today marks the beginning of that same partnership on an international level. Today, we will work to integrate increased profitability with increased safety for a growing global economy.
But as we move forward, we must ensure that product safety will not be compromised. Trading partners worldwide should strive to raise the level of safety rather than diminish consumer protection.

Over 20 years ago, CPSC, as a newly created agency, harmonized product standards so that companies could produce one product that met the safety requirements of all 50 states.

At our "Safety Sells" conference earlier this year, the toy industry and other multinational manufacturers brought to our attention that they now have a harmonizing problem on an international level. Some must produce different versions of the same product to meet the individual standards for different countries. Industry's question was simple: "Could CPSC help in harmonizing international product standards?" Well, this agency jumped at the chance.

Today we are here to talk about how we can work together and form

partnerships to make it easier to harmonize these product standards, and just as vital, to ensure the highest possible element of safety in consumer products for the international marketplace.

With industry's knack for creativity and innovation and CPSC's current track record of success, I know we can accomplish our goal of harmonizing international standards without compromising the safety of products. Today's conference not only will help establish harmonized international standards as the rule rather than the exception, it will bring CPSC's mission of saving lives and reducing injuries to the international forefront.

Today, we will hear from three world-class keynote speakers: Ambassador Mickey Kantor, United States Trade Representative; Michael Goldstein, Vice Chairman and Chief Executive Officer of Toys "R" Us; and the Honorable Ronald Brown, Secretary of Commerce.

Ambassador Mickey Kantor was sworn in as the United States Trade Representative on January 22, 1993. He is the President's foremost advisor on international trade and represents the United States as chief negotiator in major international trade negotiations. He has the responsibility for developing and implementing trade policy within our government.

Ambassador Kantor has many accomplishments, including his tireless efforts in negotiating the United States-Japan auto parts framework agreement, which averted a major trade war with Japan.

Next, I want to introduce Michael Goldstein.

One of the things I learned at our "Safety Sells" conference in March was how many companies in the private sector are actively involved in promoting product safety. It's good for consumers and it's good for business.

This progressive practice is exemplified through the leadership of Michael Goldstein, Vice Chairman and CEO of Toys "R" Us. Prior to 1983, Mr. Goldstein was Senior Executive Vice President of Lerner Stores. Preceding that, he was a partner of Ernst & Young in New York.

Last year I was honored to award Toys "R" Us as the first retailer to receive the coveted "Chairman's commendation for substantial contribution to product safety."

It gives me great pleasure to have Michael at this conference to share his views with us on the importance of government and business partnerships in successful product standard harmonization.

Secretary Ronald Brown needs little introduction. His appointment as the 30th

U.S. Secretary of Commerce was confirmed by the U.S. Senate on January 21, 1993. He went to work the very next day.

Ron Brown is a man of many skills and talents, including lawyer, negotiator, pragmatic bridge builder and the highly successful former chairman of the Democratic National Committee and 1993 inaugural committee.

Secretary Brown brings wide experience to this newest challenge of building strong private partnerships between business and government. He has been an outstanding Secretary of Commerce, serving the President in a broad capacity -- even broader than the vast jurisdiction of his department!

Secretary Brown will speak today about the importance of international trade to our economy.

Our three panels and wrap-up session at the end will provide the technical expertise for the conference. Our first panel will describe the international agreements and standards that are the foundation for product standards harmonization. The second panel, made up of representatives from four federal agencies, will discuss how each is successfully reinventing government standards. The third panel will focus on the business end of standards harmonization.

KEYNOTE SPEAKER

Mickey Kantor
United States Trade Representative
Office of the U.S. Trade Representative

Good morning to everyone. Thanks for having me here.

I'm delighted that one of our keynote speakers is Ron Brown, the best Secretary of Commerce that we ever had, and that the other is Michael Goldstein from Toys "R" Us. As a parent of four children, I want my dividend. In 26 years of purchases, I know the price is right at Toys "R" Us, but the fact is I think I deserve something back after all these years. It's a wonderful operation and, of course, has done quite well around the world. It certainly represents a part of what we are talking about here today.

What I'd like to do, with your permission, is try to put what you're doing today in a little larger context, and try to indicate to you how important what you are doing is to world trade, to our ability not only to grow jobs here in the United States, but also to formulate global growth and to make sure, of course, that we use trade as a political tool, as well as to improve our relations among nations.

When you talk about harmonizing standards, on safety as well as other areas, we talk about everything from packaging to labeling, from testing to certification. All these things are under discussion right now, everywhere from Geneva, the World Trade Organization, the OECD in Paris, in regional discussions we are having with APEC, the Asia-Pacific Economic Cooperation forum, the Summit of the Americas process, leading to the Free Trade Area of the Americas, and to our bilateral relationships from China all the way to Europe and into Latin America.

All of this is critical if we are going to create two sides of the same corner. On one side we have harmonization of standards, safety certification and testing issues. On the other side we have trade barriers. In order to deal with both sides, we can open up markets and expand trade. Frankly, we can have what I call a win-win-win situation -- safer products, removing barriers and growing jobs here in the United States. That's what this administration has been dedicated to since we came into office.

No President of the United States in this century has done more in trade than President Clinton. We have had 149 trade agreements -- bilateral, regional and multilateral -- in 30 months. Seventy are bilateral agreements in textiles and apparels, which are very important. We have had 16 agreements with Japan. The latest was a couple of weeks ago, when we reached an agreement in Geneva on autos and auto parts. On the regional level, of course, we have the Free Trade Area of the Americas. We have had the Bogor Declaration, which will open up free trade in Asia by the year 2010 for developed countries, by 2020 for undeveloped or developing countries. Then,

of course, we had the Uruguay Round, the largest trade agreement in history. In addition, we had the North America Free Trade Agreement, an agreement with China protecting intellectual property rights and many other agreements as well.

This administration came in and said we have got to do this, we have got to open up these markets and grow jobs. First, though, we've got to strengthen our own economy here at home. You can't compete in the world economy unless you strengthen your own economy at home. The President's economic plan and the earned income tax credit helped lower interest rates, create capital, fuel a capital expansion in private business, grow jobs, lower the budget deficit and lower the number of federal employees. At the same time we are increasing the number of private businesses more than at any time in history in this country. The President's plan has worked and worked well.

As you know, we've created about seven million jobs since we've been in office. Average income is rising, although median income is not rising as fast as we would like. We would like to continue to work on that. So, one part is to strengthen our economy by growing private -- not public -- jobs. We've created a higher percentage of jobs in the private economy than any administration since Warren Harding was President of the United States. The unemployment rate came down to 5.4 percent last month. That's Part I.

Part II is to continue to educate and train the American people. It does us no good to strengthen our economy if you don't take our most important asset -- our work force -- and educate and train them and provide them with the necessary tools to compete in what has become a global economy.

Part III, of course, is to take care of the global economy. We've got to compete and win again. We've got to create hope in the American people if they are to compete with the Japanese or Europeans in this ever-increasing competition around the world. That means expanding trade is critical to our economy.

This year our trade will exceed $2 trillion -- $2.2 trillion. It has gone from 24.8 percent of our economy in late December 1992 until the end of this year, when we estimate it will be over 30 percent of our economy. It's growing at a rate of 25 percent. Just this year our exports grew -- 18 percent last month -- and is growing at a rate of about 17 percent for the year. That's about the highest percentage growth in exports in American history.

Expanding trade is critical because it represents jobs. Twelve million jobs in our economy are directly related to exports, and those jobs pay an average of 17 percent more than other jobs. Trade is an increasing percentage of our economy and, of course, our globe is shrinking. At the end of the Second World War, the U.S. was 44

percent of the world's production. We're now down at 22 percent. That's good news and that's not-as-good news.

The not-as-good news is that we are not as strong and powerful or as dominant economically. The good news is that we are getting middle class consumers all over the world who will buy our products and will raise our incomes. We've got to see that as an opportunity, not a problem.

We've got to make sure that as we grow this international trading system, we try to do it in a way we did not do it after the Second World War. It used to be that we had strategic and political issues. Economic issues were only a tool by which we advanced those other two broader concerns. During the Cold War, our strategic and political concerns were such that we used trade to make sure we bolstered the economies of Japan and Europe as bulwarks against Soviet and Chinese expansionism. It was a proper policy and it worked. But in the meantime, what we did in Japan and Europe and in other areas was create multiplying sanctuary economies in a non-level playing field. Not only did it hurt us economically in the '70s as we became less and less dominant economically, it also created a sense in the American people that their government was not standing up for their interests.

Of course, what that did was hurt our ability to reach trade agreements because the American people were so cynical and skeptical regarding what their Government would and would not do either for them or on their behalf. We've tried to turn that around in three ways.

First of all, the President said that our economic security and our national security are inextricably intertwined -- we have a three-legged stool made up of economic, political and strategic considerations as we deal with other nations. We are putting economics on the same level as we have put these other considerations.

Second, we said we wanted a level playing field. As we begin to phase into the Uruguay Round, the World Trade Organization, the Free Trade Area of the Americas, the Asia-Pacific Economic Cooperation forum, or bilateral treaties, we will insist that the United States have the same access to foreign markets as foreign countries have to our markets. Simple principle. Makes good sense.

We've not followed that principle for good and sufficient reasons in the past, but as we begin to follow that principle, two or three things will happen. One, we will grow jobs here at home; two, we'll fuel global growth; and three, we'll do something very important -- we'll create credibility and, frankly, confidence in the American people. They can rely on their government to stand up for their interests in this new global economy.

Last but not least, we have to come to the recognition that if you were doing a marketing study today, you would say our markets, being four percent of the world's

population, exist outside our borders.

Let's understand where we are demographically. We are an aging population, and I am among them, unfortunately; in this job I get a little older very quickly. We are nearly at zero population growth. Our economy will never grow as fast as Asian or Latin American economies. They have younger populations, faster growing labor forces and a faster growing middle class.

But there's a pony in that closet, folks, and the pony is that those are our markets of the future. If trade creates higher paying jobs and we can sell the high value-added goods representing high-wage, high-skill jobs, that's good -- it's not bad -- that's terrific for the United States. We just have to have the confidence in wanting to compete and win. So, as we look at this we see the following: trade has become critical to our economy; the whole world is reaching standards that are leveling the playing field (I'll come back to that in a moment); and this is good for our economy because it's a new opportunity for us.

Now, where do harmonization and standards fit into this? Not only do they fit very nicely, but critically. We can't engage in a level playing field, equal trade, open up markets and get rid of trade barriers unless we harmonize standards. But as we do it, we've got to harmonize up, not down. Critical. If nothing else gets across this morning, and you will hear a lot of speakers, very bright people, certainly brighter than I, harmonizing standards up is critical to our future. It's critical to safety, it's critical to health, and it's also critical to our ability to compete and win. We can't win in a war where standards get lower. We can only compete in a war where standards get higher. So, it's a win-win situation: higher standards, more safety, protect the health of consumers around the world, and grow jobs here at home as well as globally.

As you go through your deliberations, what I would love to hear discussed, and I'm am sure you are going to do it, is how do we harmonize our standards up, how do we get our trading partners to agree to that, how do we use that to open markets, not just in the safety area -- that's critical -- or the health area, but how do we do it in packaging, labeling, certification and testing? There are all kinds of areas that all of you know more about than I do.

I guess my gentle challenge to you today is, in just a few hours, to come up with formulas we will need to follow as we proceed with these trade agreements, as we develop the Free Trade Areas of the Americas, APEC, and as we continue to develop in the World Trade Organization in Geneva, which is so critical to multi-lateral disciplines. As we use the OECD and other organizations to pursue these objectives, you can help us define what these goals will be and how we are going to get there.

All of you, I appreciate what you are doing here. I especially appreciate what a wonderful job Ann does every day for all of us. I appreciate the fact that you will spend your time talking about this public-private partnership we've got to have in order to

pursue it. It can't be done by government alone. We couldn't have gotten an auto and auto parts agreement with Japan if it were government alone. We couldn't have had a Uruguay Round Agreement if it had been the private sector alone. We've got to do this together.

Our job is to prepare the tracks and clear them for the engine of growth that is private industry. Your job is to put the proper train on the tracks. So we will work with you. We will be your advocates. We will listen to you. We will follow your dictates, as long as we agree with them, and we will work closely with you every step of the way.

I thank you for having me and I look forward to working with you. Thank you very much.

KEYNOTE SPEAKER

Michael Goldstein
Chief Executive Officer
Toys "R" Us, Inc.

Thank you, Ann.

It is indeed an honor to be invited to share the platform with Ambassador Mickey Kantor and deliver the opening remarks at this conference.

Ambassador Kantor, thank you for your efforts in reducing foreign trade barriers that frustrate American companies anxious to expand their international presence. Ambassador Kantor's efforts to protect American intellectual property rights in China, to open the auto and insurance markets in Japan and to create NAFTA are excellent examples of ways to improve market access for American companies.

Every day U.S. companies trying to export their products must work with regulators concerned with health, safety and a myriad of other regulations before these products can be exported. Therefore, this conference is very timely.

I would like to thank Ann Brown, her fellow commissioners and the entire staff of CPSC for their sense of urgency, energy and creativity in setting up this conference.

On March 28th of this year, about three-and-a-half months ago, at CPSC-sponsored "Safety Sells" conference, I indicated the need for international safety standards. Many of the representatives at that conference, including CEOs from numerous international consumer products companies, agreed that international standards would not only help U.S. industries to increase their exports, but also improve safety standards throughout the world. Ann Brown indicated at the conference that she would immediately look into this issue.

At the International Council of Toy Industries world toy conference held just one month ago, Alan Hassenfeld, CEO of Hasbro and chair of the conference, said of this issue, and I am quoting Alan, "International safety standards -- wouldn't it be amazing to have one set of quality standards worldwide." Many speakers at the conference from nations all over the world echoed Alan's comment. There was a universal plea among this group that we need international safety standards. World trade has exploded over the last 10-15 years and unfortunately, progress to date on international standards has been modest at best.

Well, when Ann Brown sees the need for action, she moves and moves quickly. That's why we are here today to address this important issue. Ann, thank you for

getting business and government leaders like Ambassador Kantor and Secretary Ron Brown focused on the need for international safety standards.

Why is this issue important? Why is it important for a company like Toys "R" Us? Why is it important for our suppliers and other manufacturers?

Toys "R" Us now has stores in 21 countries, including the United States, and will enter two additional countries later this year. Next year, we hope to open stores in two to four additional countries. We now have 618 toy stores in the United States and over 300 toy stores in other countries of the world, with our biggest store groups in Canada, the United Kingdom, Germany, France, Spain and Japan.

Toys "R" Us seeks to offer for sale only those products that meet rigorous safety standards. All merchandise we buy for the United States must conform with current CPSC regulations, FDA requirements, all federal, state and local laws and industry voluntary standards. When we are the importer of record, we insist on comprehensive safety testing by our approved testing laboratory. We follow similar types of rigorous safety procedures throughout the world. Unfortunately, standards are different in various countries, and the following problems arise.

Duplicate testing

Manufacturers selling a product to Toys "R" Us must perform different testing for different countries, and in certain countries a toy must be labeled that it has met a certain standard. The manufacturers could save lots of time and testing expenses if there were a reasonable set of worldwide standards. A simplistic answer could be for the manufacturer to select the most rigorous standard for each test and use that standard. Unfortunately, that doesn't work because there are certain country standards in place that are unreasonable, and until reasonable standards are in place, uniform testing cannot be done.

Exporting difficulties

Recently, I was in several European countries and noticed that some of the juvenile products being sold in our stores did not look as attractive nor were they as innovative as certain items we sell in the United States. I spoke to the general merchandise manager for our international division about this. He indicated to me that he agreed with my assessment but that certain United States manufacturers were not willing to enter international markets because of the different safety standards in place.

I then contacted several of the manufacturers and told them they have a unique opportunity to sell some wonderful made-in-the-U.S.A. products in our stores throughout the world. Many of these manufacturers are small in size and capitalization and indicate that the changes they would have to make to conform to certain country

requirements would probably be too costly for them to undertake. They agreed to research the issue further, but I am not too optimistic that they will move forward, or if they do it, it will be with only one or two items, not with a full line that would give them sufficient clout in terms of marketing and in-store support to make a successful entry. If there were uniform international standards, there would be a more level playing field. This would help U.S. exporters, particularly smaller, entrepreneurial companies.

Movement of merchandise from country to country

Some product lines become popular in one country well before they are introduced in other countries. Some products become successful in certain countries and fail in others. Finally, some products begin to lose their popularity in certain parts of the world, possibly because the product was introduced there earlier, whereas in other countries the product is still in a strong part of its life cycle.

For Toys "R" Us and its suppliers, the ability to move products from country to country adds to our flexibility as retailers and manufacturers. Unfortunately, if there are different safety or labeling standards involved, those transfers become very expensive. To relabel is an expensive and time-consuming task and generally makes intercountry transfers not practicable. To need further testing prior to transfer generally precludes the transfer option.

A good example of this involves Power Rangers toys. The Power Rangers toy line, which was developed in Japan and initiated in the United States and Canada, was a spectacular success. There was overwhelming demand for the product based on the success of the TV show. The manufacturer did not ship products to many other countries because they couldn't even keep up with U.S. and Canadian demand. The U.S. demand remained strong. However, after some time the Canadian interest declined significantly because of criticism of the TV show in Canada. Soon after Canadian demand diminished, we were able to transfer certain products from Canada to the United States because there were no additional safety or labeling issues to deal with.

When the Power Rangers show and product were introduced in Europe, Australia and other parts of the world, the product became a huge success in most of these countries. The demand for the initial products was very high, whereas popularity of the initial products in the United States began to wane as new, updated versions were introduced. Unfortunately, we could not transfer these initial products without some additional testing and, even more important, we had to re-label every item before we could move these goods into certain European countries. We decided the time and cost to do this extra work was not cost effective, so we had to pass on this opportunity.

There are many more examples that could be used for the toy industry, and I'm sure this affects lots of other industries as well.

Improved safety

Since there are experts on safety in all parts of the world, wouldn't it be wonderful not only if the safety information were shared on a worldwide basis, but also because of the pursuit of international safety standards, different countries would concentrate on different issues so that the very best research was done and the very best, practical safety standards were used? With international standards, there would be less concern about unsafe items being exported into countries, like the United States, with high safety standards. Wouldn't it be ideal for the toy industry to know that because of excellent, practical safety standards practiced on a worldwide basis, fewer children in this world would be harmed by unsafe toys? The same issue applies to other industries as well.

Level playing field

Although I mentioned this earlier, I think this issue deserves a fuller discussion. With international safety standards two anti-competitive issues would be eliminated. First, no country would be able to use safety standards in an unfair manner to favor domestic industries or to discriminate against products originating from certain countries. Second, manufacturers of quality, well-made products, should have less competition from similar looking, knock-off products of inferior quality. In the toy industry, this could mean the reduction and eventual elimination of poorly made toys that somewhere pass through customs checks and end up on some retailers' shelves. I assume this issue affects other industries as well.

So, with a level playing field, United States exporters, whether in the toy, juvenile products or any other industry, would have the opportunity to export more products, create more jobs and improve the standard of living by making available the best quality products at the best available prices.

In conclusion, I think this conference is an excellent step in developing international safety standards. The toy industry would like to work with CPSC and the governing safety commissions throughout the world to make international safety standards a reality. I hope CPSC will be able to work with the various European and Asian groups to move this process along. I know that David Miller, President of Toy Manufacturers of America, in his comments this afternoon will also stress both the

need for international safety standards and that the toy and allied industries would like to be leaders in this push for international standards.

Thank you.

KEYNOTE SPEAKER

Ronald H. Brown
Secretary
U.S. Department of Commerce

Good morning and welcome to this important conference. I want to thank Chairman Brown for inviting me and to thank all of you for attending. When I became Secretary of Commerce, and with that position, Chairman of the Trade Promotion Coordinating Committee, I had two important tactical goals: to reach out across sectoral boundaries and form an effective partnership with the private sector and to work more closely across agency lines to ensure that the federal government's many trade agencies worked as a unified force on behalf of the America's export firms. We have done that. I think the $40 billion in exports we have helped leverage, through Department of Commerce programs, advocacy, streamlining and targeting, speaks for itself.

But I have to wonder if maybe Ann Brown hasn't done us one better. What Chairman Brown has done is recognize the potential of her commission to be an ally in the fight to open markets for American exporters. This conference and CPSC's work to further standards harmonization around the world reflects the unabashedly pro-business stance of this administration. It also reflects the creativity we are bringing to this effort.

With tariffs and quotas falling around the world, standards are increasingly the most significant barriers to truly free trade. Meeting product standards and specifications dictated by a foreign government can be a costly burden, particularly for smaller companies or those doing business in a number of markets. A typical U.S. machine manufacturer may spend $50,000 to $100,000 a year complying with foreign standards requirements. Foreign product standards and certification requirements affect about half of all U.S. exports -- approximately $300 billion in 1993.

Recently, the Commerce Department, representatives of the European Union (EU) and private business people from both sides of the Atlantic formed something we call the Transatlantic Business Dialogue. Our goal was to bring the private and public sectors together to find ways of speeding commercial integration of America and Europe. This year we contacted over a thousand businesses in an attempt to more closely align our agenda with that of the private sector.

The results were something of a surprise. With all the press that free trade agreements -- real and potential -- had been getting, we thought that a U.S.-EU free trade agreement would be the hottest item on the list. It wasn't. What these corporations cared about more than anything else was lowering the standards and

certification barriers that transatlantic traders face every day.

We were surprised, but we were gratified as well. As the results of this survey were coming in, it was also becoming apparent that Commerce would win a long battle to persuade the EU to rethink proposed ecolabeling that might have blocked $2 billion in U.S. exports. Because of our close relationship with the private sector, the Commerce Department's priorities were already aligned with America's private firms.

The Clinton Administration understands that international trade will power America's economic growth for the foreseeable future. So, we are backing our impressive string of free trade treaties with an ongoing and comprehensive effort to ensure that standards certification barriers fall as rapidly as tariffs barriers are.

Our approach is particularly effective for two reasons: first, because we are working closely with the private sector, the people who know best which regulations provide the most formidable barriers; and second, because it is truly a coordinated interagency approach, with the Commerce Department at its center.

The Commerce Department's National Institute of Standards and Technology (NIST) is placing standards experts in key embassies around the world. These advisors wear two hats. They work with foreign standards organizations to ensure that their actions do not exclude American products, and they work with American exporters to advise them how best to meet the standards these organizations set.
By the end of the summer, we hope to add Brussels, seat of the European Union, Mexico City, and Buenos Aires, where we will focus on hemispheric standards, to our list of foreign capitals with standards experts available.

But the Commerce Department does not pursue these goals alone.

With support from the Food and Drug Administration (FDA), the United States has negotiated an agreement with Russia through which drugs and biologics approved by and manufactured in the United States can be accepted into Russia under streamlined procedures. The FDA and NIST also have ongoing exchange programs with Chinese and Russian scientists to increase mutual understanding of differing standards regimes.

The Office of the U.S. Trade Representative (USTR), Commerce and the Department of State -- with broad support from technical and regulatory agencies and many private certifiers -- negotiated bilateral agreements with the European Union for the acceptance of U.S. test results, plant inspections and, in some cases, certification of products. The resulting mutual recognition agreements will cover as much as $40 billion of U.S. exports in such sectors as information technology equipment, machinery, telecommunications equipment and medical devices.

The Federal Communications Commission amended its rules to harmonize the

standards for U.S. radio frequency emissions from digital devices with international emissions standards. This affects more than $30 billion of U.S. exports and will save manufacturers as much as $100 million a year in design and testing costs.

NIST, the Environmental Protection Agency (EPA) and the Department of Energy are participating in the new International Organization for Standardization (ISO) initiative to develop harmonized environmental management standards. NIST published an informational document on ISO environmental management standards activities in July 1994 that will enable a wider audience in both the public and private sectors to track this standards activity.

The Department of Agriculture, EPA and FDA, as members of the Codex Alimentarius, are working to harmonize international pesticide and residue tolerances to make export certification of many food products less burdensome.

NIST is managing a grant to develop a national standards system network. The network will create an electronic infrastructure linking the databases of developers, producers, distributors and users of technical standards in the United States. It will also include information on regional and international standards. In addition, NIST and the Commerce Department's International Trade Administration introduced new business information programs on the ISO 9000 quality management standards, a guide to Russian consumer protection requirements, and exporter guidance on Canadian and Mexican standards in support of NAFTA.

Because we have worked so closely with our partners in private industry, we understand that standards harmonization can actually become the leading edge of free trade arrangements. As many of you know, at last December's Summit of the Americas in Miami, President Clinton led the heads of 34 democracies in endorsing the creation of a free trade area of the Americas (FTAA). We are pledged to reach an agreement that will create the FTAA by 2005.

To help jump-start the process, Ambassador Kantor and I welcomed over a thousand officials and executives from throughout the hemisphere to Denver last month for a trade and commerce forum.

One of our first priorities at the summit was clearing the way for standards harmonization -- to create a platform upon which the formal agreement can be built. Ambassador Kantor's Trade Ministerial created a working group on standards and technical barriers to trade. This working group will compile information on conformity assessment and technical regulation bodies, recommend specific ways to enhance transparency and make recommendations on product testing and certification, with a view to mutual recognition agreements.

At the next day's commercial forum, private sector leaders had an opportunity to share with me and other ministers their views and ideas on standards harmonization.

The upshot is a hemispheric integration process in which the private sector will have significant influence and in which tangible steps toward freer trade will be taken without having to wait for formal agreements.

I'd like to thank Chairman Brown for her hard work in making this conference a success and to thank all of you for coming out to hear what we have to say and telling us what we need to know. Together we can ease exports and create jobs while creating effective standards and protecting consumers.

Thank you.

PANEL I

THE GLOBAL MILIEU:
THE FOUNDATION FOR MULTINATIONAL HARMONY

Moderator: Suzanne M. Troje, Director for Standards
Office of the U.S. Trade Representative

Panelists: Richard G. Meier, Office of the U.S. Trade Representative

Charles M. Ludolph, International Trade Administration

John Sullivan Wilson, National Academy of Sciences

Joe Bhatia, Industry Functional Advisory Committee on
Standards; Underwriters Laboratories, Inc.

THE TOOLS OF THE TRADE: SHAPING STANDARDS POLICY THROUGH INTERNATIONAL AGREEMENTS

Richard G. Meier
Deputy Assistant U.S. Trade Representative for GATT/WTO Affairs
Office of the U.S. Trade Representative

Thank you very much. I appreciate the opportunity to be here with you. It is an unusual experience for me to share the podium with my boss, Ambassador Kantor. He really did challenge the group in terms of what U.S. trade policy goals are and how they relate to the questions you are dealing with at this conference. I will try to fill in the very few blanks that he didn't cover in his talk.

I would like to briefly describe the series of international agreements that really provide a foundation for doing some of the things that were described by Ambassador Kantor and the needs described in the talk we just heard from Mr. Goldstein. I think it will serve as a foundation for the remarks of the other panelists.

These agreements deal with both standards themselves and their development, whether they be voluntary standards, or in our terms, regulations that are mandatory standards having the force of law. These agreements deal with the matters of testing and inspections, the type of problems Mr. Goldstein described in his presentation.

This whole range of issues has become known as conformity assessment. We frequently find that international trade problems relate as much, if not more, to conformity assessment as they do to the specific standard or regulation against which the product is tested.

The Technical Barriers to Trade Agreement is our most fundamental agreement. It was originally negotiated during the Tokyo Round of trade negotiations, which was recently renegotiated and expanded as part of the Uruguay Round of multilateral trade negotiations and is now part of the World Trade Organization (WTO) agreement.

I should note that the Tokyo Round code was adhered to by only 45 countries. As part of the World Trade Organization, this agreement and its obligations and commitments are now required of all WTO members -- as of today, around 100 countries. We expect that to increase to about 145 when countries complete their ratification of, or in some cases accession to, the WTO, if not by the end of this year, next year. That group of countries covers all but a very small proportion of world trade.

Let me briefly tell you what the major objectives and commitments of the Technical Barriers to Trade Agreement are and how they apply in the other agreements that I will briefly note. First, standards or conformity assessment procedures are not to be used as unnecessary barriers to trade. Second, the application and development of

standards shall not be used to discriminate either vis-à-vis domestic producers versus foreign producers or one group of foreign producers versus another. Finally, the use of international standards is to be encouraged. This is a long-term goal. Obviously, if more countries and industries use international standards, the process of harmonization becomes nearly automatic.

The process of harmonization as a long-term goal is also encouraged in these agreements. The basic principles of the agreement noted above have now found their way into a number of other agreements. Foremost of these is NAFTA and before that, the Canadian Free Trade Agreement, which builds upon the Tokyo Round Agreement and expands and intensifies it in terms of a smaller group of countries -- the three countries of NAFTA. Thus, we could tailor that agreement to meet the special needs of that group. Suzanne Troje is really the expert here, so I won't tread on her territory too much.

As Ambassador Kantor noted, we are also discussing standards issues in the Asian-Pacific Economic Cooperation forum (APEC). Toys as well as processed foods are among the sectors being looked at as a pilot project. Also in APEC, there has been a great deal of work to examine and identify the standards requirements in the various nations of that region, so there is a great improvement in our degree of knowledge of the problems and requirements that exporters face in that region.

As Ambassador Kantor also noted, we are starting to negotiate the Free Trade Agreement of the Americas stemming from the Miami Summit and more recently, the Denver meetings. Standards are an issue there, too. We are in the very early stages of that process; we have not yet built our objectives or negotiating positions. We will start that very soon, so for those interested in that region of the world, it's a good chance to give us your ideas and advice.

We also are negotiating a free trade agreement with Chile, basically an extension of the NAFTA. We foresee that the standards chapter of the NAFTA will be extended to Chile, probably without extensive revision, although that's certainly a question we can address as we go through it. Standards also are an issue in a host of bilateral arrangements too numerous to mention here.

These agreements, in particular some of ones we now are looking at in APEC and Latin America, provide a chance to use American leadership to convince these countries to use or adapt themselves to U.S. standards and U.S. regulatory approaches. This is not to say we know best, but certainly we want to advocate our system to these countries. That, too, would be a step of easy harmonization. If we can present our system -- voluntary or regulatory -- to these countries, I think we will improve our trading relations and make it a lot easier to trade with these nations. So, it's a good opportunity to use American leadership in the standards system as we negotiate these agreements.

Finally, I want to stress that throughout this process of negotiation, we depend on a cooperative relationship with our private sector, consumer groups, labor groups, industry groups, standardizers, testers and the regulatory community. I particularly want to commend the Consumer Product Safety Commission and its staff for the efforts they have made in the negotiation and implementation of the agreements I have mentioned and their continued participation in the negotiations underway.

I will also just make one final note. International cooperation, as well as domestic cooperation, is an important tool in achieving success in this area. Regardless of your industry, regulator or consumer group, as you deal with your foreign counterparts, encourage them to advocate positions that go in the direction of what the United States is trying to accomplish. Your individual opinions as to which goals are most important may differ, but it's very important to develop an international constituency for some of the goals identified here today and in your ongoing work.

I think I will close there. I am available for questions at the end of the panel. Thank you very much.

CREATIVE CONFORMITY: THE EUROPEAN EXPERIENCE

Charles M. Ludolph
Director, Office of European Union and Regional Affairs
International Trade Administration

A few days ago, I attended a small meeting of U.S. industry executives who were deciding how much time they should put into international standards development activities. After much discussion on the importance and growth of international standards, one of the executives expressed frustration. He observed that all the presentations included statistics showing substantial growth in international standards. Why, then, he asked, wasn't one of his customers or government procurement contracts specifying international standards in their contract negotiations? No one in his experience had ever asked him to fulfill a contract to an International Organization for Standardization (ISO) standard, and he wondered what people were doing with these proliferating international standards and why he should spend money on them. Obviously, these days, resources can only support what is actually used in the marketplace. Business wants to know where and when international standards are applied, as well as what they are.

This little vignette is played out again and again across the country by business persons wanting to take the next step in being competitive and deciding whether to design their product to a standard or change a standard to reflect their design. I think this is the starting context for our discussions in this conference and recommendations to the Consumer Product Safety Commission (CPSC) on its program in international standards to protect the consumer and support business.

There are many explanations to the paradox. The one I want to focus on here is very relevant to CPSC. International standards are only useful if the market place validates them by using them. Regulatory authorities like CPSC have enormous impact on where, when and how international standards are used in the United States. Many are the international standards that successfully bring together producers' and consumers' interests that fall into disuse and neglect because a code, regulatory body or government does not accept the standards. Therefore, I will focus my comments on how the European Union (EU) is using standards to open the 15 member state markets to each other by harmonizing regulatory requirements and what that implies for the United States.

In 1989 or so, the European Union introduced a new approach to regulating the safe performance of consumer and industrial products, ranging from toys to machines. Unlike the traditional approaches to product performance regulation, where government reserved the right to approve a product fit for sale in the market or relied on manufacturers to attest that product met legal requirements, the European Union introduced a system of government-appointed, private sector "for profit" product

certifiers located only in Europe. Moreover, Europe adopted a policy that its regulators generally would rely on voluntary regional product standards and test methods developed by the private sector. But there is no consistent policy for taking those regional standards to support international activities. This all leads to pre-market approvals and marking of products to a minimum level of safety harmonized among all 15 members.

While Europe has developed a single legal environment for pre-marketing approvals, there is no unified approach for post-marketing surveillance and enforcement. Moreover, the responsibility of insurance companies to uphold product liability, workers compensation claims and other tort issues has not been resolved or harmonized by these new regulations, nor is the role of international standards, or even regional standards, in these contexts resolved.

The point I want to lead you to in this summary of Europe and its efforts to make a single market with laws and standards and product approval marks is that important levels of regulatory activity were ignored. That is a problem in marketing products, reducing costs of doing business and regulation. It is not clear today, in 1995, that the uses of international standards in each national economy in Europe were effectively harmonized in all the ways that a market is regulated, particularly in post-marketing surveillance. It is also true that there is a strong interdependence between international standards and national regulations.

Another, more stark way to summarize the experience of Europe is that you can develop an international standard and harmonize approvals around that standard, but you still may not develop effective market access if the marketplace, and particularly the regulators, insurance companies and governments integrate that standard into their post-market regulatory oversight.

Voluntary standards, after all, are a thing of commerce and are developed to support trade. The very existence of voluntary international standards speaks to the fact that several nations saw the merit of reaching consensus on a technical specification that helps commerce. It does not, however, guarantee that standard will be used by consumers, regulators and procurement contractors. That is a very important and key step in the making of a single European market, as well as facilitating trade among larger trading groups.

Since 1989, U.S. businesses and regulators have tried to adapt to these innovations. Europe's system of accreditation of laboratories and ISO 9000 registrars, close government oversight, supervised product standards development, and limited access to required test procedures has meant non-European businesses and governments have had to adapt to these changes at considerable expense. European regulatory systems frequently diverge from that of the U.S. and other countries. Imports into the United States reflect these differences. The demands for harmonization are growing from the marketplace; U.S. multinationals are demanding that U.S. regulators

create one standard and one approval to reduce the U.S. multinationals' costs.

Secretary Brown and the staff of the Department of Commerce recognized several months ago that there were gaps in our ability to deal with international trade regarding technical requirements. Trade agreements that recognized international standards answered only part of the problem of market access. By the same token, support of the development of international standards did not address market access where a government procurement regulation or safety regulator preferred only a national standard or technical barrier. Steps had to be taken to make regulators aware of the international consequences of their decisions.

The International Trade Administration (ITA) of the Department of Commerce, with the European Commission, developed a transatlantic regulatory cooperation agreement that raises market access and regulatory requirements to a higher focus in the U.S.-EU trade agenda. This transatlantic regulatory cooperation is implemented in the context of the overall Transatlantic Declaration of 1991, overseen for its implementation by the U.S. State Department's sub-cabinet meeting and coordinated for the U.S. Government by the ITA. The goal of this cooperation is to see that resources and priorities are placed in regulators' hands to take account of the international implications of their domestic programs and to protect the safety of their market. It would be very important for CPSC to work within this cooperative context to expand the regulatory cooperation between the U.S. and EU and increase the effect of international standards harmonization.

Another gap in international relations that Secretary Brown has filled is in the area of close coordination of business policy with the business community. The Secretary has recently launched a transatlantic business dialogue with the European Commission, which is comprised of several score company CEOs whose advice will lend a strategic viewpoint to U.S. and EU policy-making. It is key that business interests become part of the development of the new approach to market access.

Recommendations for CPSC

1. Where necessary, support bilateral negotiations with Europe and other countries to generate mutual recognition agreements covering testing and inspections.

2. Consider the potential for recognizing and relying on accreditation systems and independent testing laboratories that support sales in the U.S. market.

3. In dealing with foreign regulators, adopt positions that promote the lowest cost product certification requirements commensurate with product risk.

4. Consider the potential for international harmonization of standards and other regulatory requirements with countries that involve heavy U.S. exports and

imports.

5. Consider the minimum necessary surveillance and enforcement systems available in foreign countries that will satisfy high levels of international trade.

6. Finally, support efforts of the Trade Promotion Coordination Committee's national export strategy to reduce requirements on U.S. exporters for exporting to foreign markets where surveillance systems are adequate.

TRADE, STANDARDS AND U.S. PERFORMANCE IN GLOBAL MARKETS

John Sullivan Wilson
Visiting Fellow, Institute for International Economics
Project Director, Standards, Conformity Assessment and Trade Policy Study
National Research Council

It is a great pleasure to be here today. This conference is extremely timely. The Commission deserves a great deal of credit for sponsoring such a gathering.

I will be speaking here today about two studies that I have directed: "Standards Conformity Assessment and Trade: Into the 21st Century," a report for the National Research Council (NRC), and a new work, forthcoming this fall, "Standards and Asia Pacific Economic Cooperation" for the Institute for International Economics. My remarks will be based on the results of these two efforts. They do not necessarily reflect, however, all views of the two organizations with which I am affiliated.

The United States is the most productive and competitive nation in the world. This is due, in part, to a high degree of economic efficiency in our domestic economy. We've made great progress in building a competitive economic environment for workers and firms. Corporate restructuring and deregulation during the past decade have produced many benefits. This includes an acceleration of technological advance. The U.S. has led the world in reducing unnecessary rules and regulations that block firms and workers from taking advantage of our creativity and technological edge.

We have removed regulatory controls in the transportation, energy and telecommunication sectors, for example. Continued progress is needed if we are to achieve higher levels of productivity and economic growth. This will come, in part, through creative legislative and executive branch initiatives to remove the remaining costly barriers to productivity, many of which relate to standards and conformity assessment regulations. National economic success also depends on the comparative advantages U.S. firms enjoy in world markets. We need cost-effective and innovative ways to support U.S. exports. The government must also continue to exercise leadership in the global trade community by aggressive action to reduce technical barriers to trade.

NRC Report: Discussion and Recommendations

The NRC report referenced above offers a unique analysis, I think, of these subjects. We recommended ways to support both domestic policy reform and success of U.S. products in global markets. We concluded, after 18 months of research and study, that the U.S. standards-development system serves the national interest extremely well. Our domestic policies and procedures for assessing conformity of

products and processes to standards, however, require urgent improvement.

In addition, the U.S. should recognize the strategic importance of standards and conformity assessment systems in supporting national trade objectives. An innovative and aggressive U.S. trade policy is necessary to meet challenges of the post-Uruguay Round environment. U.S. policy should better link standards, conformity assessment and trade objectives. At the same time, we should work to reduce technical barriers to trade, especially those related to discriminatory testing and certification rules overseas. The U.S. should continue to exercise leadership by promoting the use of mutual recognition agreements (MRAs).

Conformity Assessment

The U.S. conformity assessment system has become complex, costly, and burdensome to national welfare. Unnecessary duplication and complexity at the federal, state, and local levels result in high costs for U.S. manufacturers, procurement agencies, testing laboratories, product certifiers and consumers. Government should retain oversight responsibility for critical regulatory and procurement standards in areas of public health, safety, environment and national security. The assessment of product conformity to those standards, however, is performed most efficiently by the private sector. Government should act only in an oversight capacity. The government should evaluate and recognize private-sector organizations that are competent to accredit testing laboratories, product certifiers, and quality system registrars.

> Recommendation 1: Congress should provide the National Institute of Standards and Technology (NIST) with a statutory mandate to implement a government-wide policy of phasing out federally-operated conformity assessment activities.

NIST should develop and implement a national conformity assessment system recognition program. This program should recognize accreditors of testing laboratories, product certifiers and quality system registrars. By the year 2000, the government should rely on private-sector conformity assessment services recognized as competent by NIST.

> Recommendation 2: NIST should develop, within one year, a ten-year strategic plan to eliminate duplication in state and local criteria for accrediting testing laboratories and product certifiers. NIST should lead efforts to build a

network of mutual recognition agreements among federal, state and local authorities.

After ten years, the Secretary of Commerce should work with federal regulatory agencies to eliminate remaining duplication through preemption of state and local conformity assessment regulation.

Standards Development

Federal government use of the standards developed by private standards organizations in regulation and public procurement has many benefits. These include lowering the costs to taxpayers and eliminating the burdens on private firms from meeting duplicative standards in both government and private markets. Not every public standard can be developed through private-sector processes. Government should rely, however, on private activities in all but the most vital cases involving protection of public health, safety, environment, and national security.

Efforts by the U.S. Government to leverage the strengths of the private U.S. standards system, as outlined in Office of Management and Budget (OMB) Circular A-119, "Federal Participation in the Development and Use of Voluntary Standards," are inadequate. Cooperation in developing and using standards requires a clear division of responsibilities and effective information transfer between government and industry. Improved institutional mechanisms are needed to effect lasting change.

Recommendation 3: Congress should enact legislation replacing OMB Circular A-119 with a statutory mandate for NIST as the lead U.S. agency for ensuring federal use of standards developed by private, consensus organizations to meet regulatory and procurement needs.

Recommendation 4: The director of NIST should initiate formal negotiations toward a memorandum of understanding (MOU) between NIST and the American National Standards Institute (ANSI). The MOU should outline modes of cooperation and division of responsibility between ANSI, as the organizer and accreditor of the U.S. voluntary consensus standards system and the U.S. representative to international, non-treaty standard-setting organizations and NIST, as the coordinator of federal use of consensus standards and recognizing authority for federal use of private conformity assessment services. NIST should not be excluded from negotiating MOUs with other national standards organizations.

In addition, all federal regulatory and procurement agencies should become dues-paying members of ANSI. Dues will support government's fair share of ANSI's infrastructure expenses.

International Trade

Expansion of global trade is increasingly important to economic growth, productivity, and high-wage employment opportunities in the United States. The reduction of barriers to international commerce and aggressive promotion of U.S. exports must continue to be the fundamental objectives of a post-Uruguay Round trade strategy. At the multilateral level, the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) achieved significant progress in reducing barriers related to discriminatory standards and national product testing and certification systems.

However, there is evidence to indicate that the growing complexity of conformity assessment systems in many nations threatens to undermine future global trade expansion. U.S. exporters face high costs in gaining product acceptance in multiple export markets. Many nations impose duplicative, discriminatory requirements for product testing, certification and quality system registration. The European Union's (EU) mechanisms for approving regulated products, in particular, continue to pose serious barriers to expanded export opportunities for U.S. firms. Clearly, the severity of these obstacles varies by industry sector. From a national perspective, it is important, however, to achieve a rapid, negotiated removal of EU barriers. This will serve both to expand trade opportunities and to help promote the success of similar negotiations between the United States and other trading partners, especially those in the emerging nations of the Asia-Pacific Economic Cooperation (APEC) forum.

Agreements between governments to recognize national conformity assessment mechanisms have a great potential to facilitate trade. A network of global mutual recognition agreements would enable manufacturers to test products once and obtain certification and acceptance in all national markets. At the regional level, for example, a successful conclusion to discussions within the APEC forum on an MRA would provide significant new opportunities for U.S. trade expansion in rapidly growing markets of Asia.

> Recommendation 5: The Office of the U.S. Trade Representative (USTR) should continue ongoing mutual recognition agreement negotiations with the European Union. The USTR should also expand efforts to negotiate MRAs with other U.S. trading partners in markets and product sectors that represent significant U.S. export opportunities. Priority should be given to concluding MRAs on conformity assessment through the Asia-Pacific Economic Cooperation forum.

It is possible that negotiations with Europe may not reach a timely or successful conclusion. Under these circumstances, failure by the Europeans to remove trade barriers in conformity assessment within a reasonable period should lead to unilateral action, as authorized under U.S. trade laws. Moreover, the USTR should use the full potential of targeted action on a unilateral basis under our laws, as appropriate, to remove barriers in other markets.

> Recommendation 6: The USTR should use its authority under Section 301 of

the Trade Act of 1974 to self-initiate retaliatory actions against foreign trade practices involving discriminatory or unreasonable standards and conformity assessment criteria. In particular, if U.S.-EU negotiations do not succeed within two years in securing fair access for U.S. exporters to European conformity assessment mechanisms, the USTR should initiate retaliatory actions under Section 301.

Innovative export promotion programs have the potential for significant, long-term economic benefit. By providing technical assistance to countries in emerging markets as they construct modern standards and conformity assessment systems, the United States has a unique and valuable opportunity to facilitate future world trade.

Recommendation 7: NIST should develop and fund a program to provide standards assistance in key emerging markets. The program should have four functions:

a) provide technical assistance, including training of host-country standards officials, in building institutional mechanisms to comply with the Agreement on Technical Barriers to Trade under the Uruguay Round of GATT;

b) convey technical advice from U.S. industry, standards developers, testing and certification organizations and government agencies to standards authorities in host countries;

c) assist U.S. private-sector organizations in organizing special delegations to conduct technical assistance programs, such as seminars and workshops; and

d) report to the export promotion agencies of the Department of Commerce (such as the U.S. and Foreign Commercial Service) and the USTR regarding standards and conformity assessment issues affecting U.S. exports.

Future Challenges and Opportunities

The nation's ability to respond to new developments in standards and conformity assessment will influence our future in many ways. There is the urgent need for increased federal data-gathering and analysis on standards and conformity assessment. We require an ongoing capacity to analyze the economic effects of developments in domestic and international standards and conformity assessment systems. This new capacity would support improvements not only in our domestic systems, but also in our ability to monitor and anticipate international developments in key emerging areas such as environmental management standards.

In addition, wide dissemination of information to U.S. firms about standards and

certification requirements in global markets is needed to improve prospects for future U.S. export expansion. Detailed and readily available information about international developments is especially important for our small and medium-size firms wishing to compete in global export markets.

> Recommendation 8: NIST should increase its resources for education and information dissemination to U.S. industry about standards and conformity assessment. NIST should develop programs focusing on product acceptance in domestic and foreign markets. These efforts should include both print and electronic information dissemination, as well as seminars, workshops and other outreach efforts. Programs should be conducted by NIST staff or by private organizations with NIST cooperation and funding.
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> Recommendation 9: NIST should establish a permanent analytical office with economics expertise to analyze emerging U.S. and international conformity assessment issues. The office should evaluate and quantify the cost to U.S. industry and consumers of duplicative conformity assessment requirements of federal, state, and local agencies. To support the work of the USTR and other federal agencies, including those involved in export promotion, it should also collect, analyze and report data on the effects of foreign conformity assessment systems and regulations on U.S. trade.
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> Recommendation 10: The USTR's post-Uruguay Round trade agenda, including work through the World Trade Organization, should include detailed analysis and monitoring of emerging environmental management system standards and their potential effects on U.S. exports. Technical assistance should be provided to USTR by NIST.

Concluding Remarks

My recent work at the Institute for International Economics supports these conclusions. In particular, U.S. participation in talks through the APEC forum on achieving open trade in the region by 2020 is vital to our economic interests. The success of the APEC talks in trade liberalization and facilitation are directly related to efforts such as those in standards and conformity assessment reform. Both the developed and developing members of APEC share a common interest in deregulation. As global tariff rates have fallen and non-tariff barriers to trade are reduced, technical barriers become relatively more important obstacles to trade. Approximately 15 percent of all notifications to the GATT of non-tariff barriers, for example, involve some form of technical regulation.

The most important work of APEC on standards and conformity assessment involves MRAs on a broad range of regulated product sectors. To date, APEC has focused on an overly complex set of issues. These include reform in procedures for regulated products and non-regulated sectors over which government exercises little

control. In order to achieve open trade in the region by 2020, APEC should substantially reorder the standards work program at Osaka.

Specifically, APEC should do the following: 1) delegate all work on standards, including plans to align national standards with international ones to private sector groups in the Asia-Pacific; 2) announce at the leaders meeting in Osaka in November immediate launch of MRA negotiations in autos and auto parts, transportation equipment, chemicals, medical devices and other infrastructure-related sectors; (3) create an APEC technology fund to assist in financing infrastructure projects to support MRAs; and 4) establish a new standards panel of government and industry experts to monitor, assess and help mediate technical barrier to trade disputes in the region. These measures would substantially strengthen APEC's standards program and likelihood of success of the Osaka meeting this November.

WINNING THROUGH INTERNATIONALIZATION: AN INDUSTRY VIEW

Joe Bhatia
Vice Chairman, Industry Functional Advisory Committee on Standards (IFAC2)
Vice President, Underwriters Laboratories, Inc.

Good morning. My name is Joe Bhatia and I am the Vice Chairman of the Industry Functional Advisory Committee, IFAC2. For those of you who may not know, IFAC2 is made up of industry representatives from various commercial sectors who are appointed by the U.S. Trade Representative (USTR) and is primarily responsible for providing the USTR perspective to private sector industry regarding trade and standardization certification.

Several of you on the panel and in the audience know that I am also a vice president of Underwriters Laboratories (UL) and served for five years in the Washington area, working with the U.S. Congress, trade associations and government agencies, particularly the U.S. Consumer Product Safety Commission (CPSC). Today, however, I am here on behalf of IFAC and will present that body's views on the subject of this conference.

From a business perspective, the issue of international standards is really very straightforward. It is all about selling products and services. One key to competitiveness today is to be able to sell the same or highly similar products and services in many different markets.

International Approach

Internationally, harmonized standards play an obvious role. When the same product or service requirements are used in multiple markets, a single product or service can be designed for all of those markets. Eliminating the variations needed to meet unjustifiably different requirements brings costs down and expands the potential buyer population through lower prices. Most of us have heard the term "economies of scale." They really do apply in this context.

We should recognize, however, that internationalization in markets, standards, and other aspects of business is not a new phenomenon. Rather, it is a natural extension of a process that has been going on since the very beginning of commerce. Internationalization is simply the latest step in a process that has seen markets expand and homogenize from villages to valleys, provinces, countries and, now, regional trading blocks, like the North American Free Trade Agreement (NAFTA) countries or legislated single markets, like the European Union (EU).

We should also recognize that internationalization in business takes on many

different forms, depending on the product sector and the geography. Let me give you two extremes right here in the U.S. as examples. As recently as 1992, my company, UL, was aware of a significant industry in the U.S. that had yet to take standards-writing beyond the individual company level. Yet, at the other extreme, sectors such as the information technology and telecommunications were very active in establishing a single set of requirements worldwide for certain products.

Geographically, internationalization in standards and product acceptance methods has become intimately linked with trade agreements. In Europe, the now-famous single internal market established originally under the Treaty of Rome has had a major impact on unifying standards and conformity assessment procedures across the continent. A supranational legislative process was used to effect standards harmonization.

In North America, under NAFTA, market forces aided by government commitment to reducing trade barriers are used to harmonize standards. Often, within these larger trading blocks or markets, even before the formal structures are established, industry needs cause harmonization of binational standards and product acceptance procedures. A typical example is the binational harmonization taking place between the U.S. and Canada via standards-harmonization efforts of UL and the Canadian Standards Association.

Internationalization is at the same time quite simple and extremely complex. The result industry usually seeks is quite simple -- one product acceptable in all markets through one standard. The complexity lies in tracking and staying current on national and local standards, legal requirements, installation and use codes, consumer regulations, commercial laws and, finally, societal and governmental expectations. Doesn't it sound simple? Still, with industry support and involvement of other constituencies, the standards-writing organizations are fast working towards standards harmonization and trade liberalization.

Industry Approach

How does industry approach standards harmonization and product acceptance issues to achieve success? The answer: not in any single way. When it comes to bringing standards together, a sectoral approach is preferred by industry. Let me make a few observations.

Essentially, manufacturers trying to sell their products in local and foreign markets want to avoid delays and costs associated with compliance to multiple standards and gaining product approval in each country. It is recognized that international standardization helps in getting products easily exported and accepted. Perhaps the most significant activity from the industry perspective is working actively in the two leading international standards organizations: the International Electrotechnical Commission (IEC) and the International Organization for

Standardization (ISO).

Early involvement in these organizations' projects is desirable in order to have an impact on their deliberations. And, of course, these are not rapid processes. Even slower is the adoption of international standards by most countries. In the U.S., while the pace for adoption varies by industry, it is changing overall. Quite a number of U.S. standards have been harmonized to varying degrees with international standards because U.S. industries have expressed the willingness to move in this direction.

Industry and user needs are the key to the harmonization of international standards. A key question is always, "Is industry in that sector seeking harmonization, and if so, to what level?" Often harmonization with international standards may require the involved industries to modify specific products, which may require considerable investment of time and money. Sometimes it becomes difficult for manufacturers to make changes that are costly and add little or nothing to the safety or marketability of the products involved. And yet, as the motivation grows to seek foreign markets -- excited by EU, NAFTA and other economic global developments -- conformity to international standards becomes a prerequisite.

Not only will product standards need to be changed to harmonize with international standards, efforts often will be needed to revise building, mechanical and electrical installation codes where conflicts with international standards exist. For example, when the U.S. information technology industry opted to harmonize the U.S. national safety standard UL 1950 with the international standard IEC 950, the National Electrical Code and the National Fire Protection Association Standard 75 also were revised to eliminate conflicts.

Industry Recommendations for CPSC

Although each sector may have its unique needs and preferences, in general, industry can offer the following recommendations for CPSC relative to harmonization of standards internationally.

Industry wants CPSC to get involved where appropriate and where the products involved fall under the Commission's mandate. Industry recognizes that participation in standards harmonization and product acceptance mechanisms will lessen the burden of CPSC to take costly actions after products have been imported into the U.S. market. This can prevent and avoid costly recalls, public notifications and education activities, as well as legal actions.

Industry wants government agencies and the private sector, as well as international standards processes, to work together. Otherwise, repetitive efforts are initiated and undesirable barriers to trade emerge.

Industry wants the involved parties to cooperate to develop one unified U.S. position or, if possible, one North American position, on an international standard or draft proposal. This means organizations such as the industry trade associations, American National Standards Institute, standards-writers and the government agencies such as the FDA, FCC and CPSC all must work together through the U.S. Working Group or Technical Advisory Group to produce a uniform U.S. position in order to represent its interests in the IEC or the ISO.

Industry expects CPSC and other involved Federal agencies to help create a level playing field in the U.S. In the case of CPSC, this means that all products coming into the U.S. have the same level of safety as expected of the locally manufactured goods. U.S. industry, regulatory authorities and certification organizations have an important role in assuring that imported products in the U.S. marketplace conform to safety requirements and are capable of being installed in accordance with the nationally recognized building, electrical and other codes. Private sector programs have benefited product users and authorities whose responsibility it is to enforce the codes. Industry recognizes that we must all be prepared to face more compromises for the sake of harmonization. Again, the degree of compromise must vary with the product sector and the level of risk involved.

Where appropriate and needed, industry supports government agency and private sector bilateral arrangements with U.S. counterparts to facilitate trade, resolve problems and handle safety issues. For example, CPSC and the Canadian Bureau of Product Safety have established an agreement covering consumer products in the U.S. and Canada. My organization alone has over 35 such bilateral arrangements globally to facilitate product and quality work. Industry needs more of these types of facilitations to avoid duplicative work and reduce trade barriers.

Conclusions

Although only a limited number of the internationally harmonized standards are in effect in the U.S. today, there is no doubt in my mind that the standards development process will be reacting to "free trade" for many years to come, until the new equilibrium level is found.

Industry and other private sector organizations will play a critical role. Indeed, where consumer protection and product safety are involved, cooperation between parallel bodies from the public and private sectors in the U.S. and other countries must occur. This will assure maintenance of the effectiveness of public safety systems in respective nations while trade is enhanced.

For industry, winning through internationalization today means understanding the changing trade and harmonization landscape and converting that knowledge into higher

value products and services for customers worldwide.

Thank you.

PANEL II

REINVENTING GOVERNMENT STANDARDS: SUCCESS STORIES

Moderator: Ronald L. Medford, Assistant Executive Director for Hazard Identification and Reduction, U.S. Consumer Product Safety Commission

Panelists: James J. McCue, Jr., Food and Drug Administration

Kurt H. Edwards, Federal Aviation Administration

Belinda L. Collins, National Institute of Standards & Technology

Douglas L. Noble, U.S. Consumer Product Safety Commission

MAKING MEDICAL DEVICES THROUGH INTERNATIONAL COOPERATION

James J. McCue, Jr.
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Office of Science & Technology, Center for Devices and Radiological Health
Food and Drug Administration

Background

Medical device technology is recognized by the U.S. Department of Commerce as one of the fastest-growing industrial sectors. Domestic manufacturers have traditionally dominated the world market, earning an impressive 52 percent of the world market for medical devices and creating a favorable balance of trade of $4.5 billion. Furthermore, more than 80 percent of all the devices invented in the past 40 years, like the pacemaker, originated in the United States.

The Food and Drug Administration (FDA) is responsible for the regulation of medical devices with the specific charge to protect the public health by ensuring the safety and effectiveness of medical devices. Within FDA, this task falls to the Center for Devices and Radiological Health (CDRH).

Consensus Standards

CDRH was established in 1972 and has been active in consensus standards development since that time. CDRH, with a number of other organizations, was instrumental in the establishment of the Medical Device Standards Board within the American National Standards Institute (ANSI). We are also active at the policy level in the major consensus standards developing organizations, having representatives on the Board of Directors for ANSI, ASTM, the Association for the Advancement of Medical Instrumentation (AAMI) and the National Committee for Clinical Laboratory Standards.

During 1994, 192 CDRH staff members served as primary and alternate representatives to 38 consensus standards organizations and 440 committees and subcommittees. Throughout the year, our representatives participated in 317 meetings, and CDRH actively reviewed and provided comments on 286 draft standards reflecting FDA's position on issues.

The international component of this effort encompasses nine organizations, 113 efforts, 77 representatives and 134 draft standards. The effect of scarce resources, the unified European market and the North American Free Trade Agreements (NAFTA) has shifted the emphasis of CDRH's consensus standards program toward international standards, with a further shift from domestic, single

product (vertical) standards to a greater emphasis on international, problem-oriented (horizontal) standards.

Mandatory Standards

In the radiological health area, the CDRH experience with ten mandatory standards yields an average development time of three years and 40 full-time-equivalent employees (FTEs), with a yearly enforcement cost of 24 FTEs. For medical devices, we have published our first proposal for a mandatory standard, and perhaps a phrase from the motion picture industry best characterizes its development -- "Ten years in the making!"

Why We Participate in Consensus Standards Development

CDRH encourages participation in the development of consensus standards as a useful adjunct to the regulatory controls available to address medical device and radiological health problems and safety concerns. The development of a consensus standard involves many groups interested in the solution of a product or generic problem, effectively multiplying the resources available to FDA to resolve that problem. The revision procedures of consensus standards organizations ensure periodic review and reaffirmation of completed standards. Additionally, the open, public discussion of the problems and/or safety concerns that occurs in the consensus process very often results in manufacturer and/or user implementation of solutions long before the specific standard is completed.

More than one-third of CDRH's standards liaison representatives are in the Office of Device Evaluation, the office that approves medical devices. The guides used in clearance of medical devices are called reviewer guidance documents, and a review of 170 of these documents yields the fact that more than 370 consensus standards are specifically referenced. This does not include the cases where test protocols in the guidance documents match test methods in draft consensus standards or where a number of acceptable consensus standards exist.

In the area of compliance, two of our labeling regulations use three existing consensus standards and four of our compliance policy guides reference five existing consensus standards. We currently train our inspectors in the area of device sterility using International Organization for Standardization (ISO) standards, which are based on AAMI standards. We are preparing to revise our policy guide on sterility to include this series of ISO standards.

Medical device sterility is an area of significant interest to CDRH, so let us trace our involvement in this area and its output to explain how we try to ensure a resulting standard that we can use. The AAMI Sterilization Standards Committee, co-chaired by a CDRH representative, is composed of 21 working groups covered by 13 CDRH representatives. Documents are approved at the working group and then at the Standards Committee level. Within AAMI, further approval is required at the Standards Board and Board of Directors level. CDRH has representatives on both, giving us four "shots" at each standard. AAMI standards are then submitted to ANSI for adoption,

where we have the opportunity to affect these documents through our representatives on the Medical Device Standards Board and the Board of Directors. An ANSI/AAMI standard is submitted to ISO technical committee 198, co-chaired by a CDRH representative, and from the committee level to one of 20 working groups, covered by six CDRH representatives.

As unlikely as it appears, if an ISO standard is published with which we do not agree, then certainly we have had the opportunity to hear and debate the issues that are in contention and thus strengthen our position.

Authority

What authority do we, as a regulatory agency, have for such involvement in consensus standards? Office of Management and Budget Circular A-119, now in its third or fourth incarnation, urges federal agencies to use consensus standards whenever possible to accomplish their missions. The circular also urges the use of international standards. The General Agreement on Tariff and Trade (GATT) establishes an agreement between signatory nations to use international standards whenever possible.

As far as participation in outside standards-setting activities is concerned, our Administrative Practices Regulation covers that at 21 CFR Part 10.95.

Conclusion

The CDRH participates in and uses consensus standards because they work! We multiply the expertise base available to us for very little cost, and the resulting documents are usable in our programs. In fact, on June 19 of this year, we sponsored an open public workshop to discuss our proposed use of third-party certification for medical devices. Such certification would use consensus standards extensively.

The CDRH stresses international standards in its program because, as my youngest son says, "that's where it's at." We urge our sister agency CPSC to join us in this exciting new approach to regulation.

OPEN DIALOG: SAFER SKIES

Kurt H. Edwards
International Program Analyst, Office of International Aviation
Federal Aviation Administration

First, let me thank Chairman Brown for inviting me to speak here today. I appreciate the opportunity to share with the Commission and this conference the Federal Aviation Administration's cooperative efforts with its foreign counterparts.

The FAA has enjoyed a long history of cooperation in airworthiness safety regulation with foreign civil aviation authorities (CAAs). We have essentially developed a bilateral regime by which we work with competent authorities in aircraft-producing countries to promote high levels of international aviation safety. Our efforts can be divided broadly into two categories. The first area is a network of bilateral agreements that facilitate reciprocal acceptance of certification work. The second category of cooperative initiatives -- and a more recent development -- is the agency's program to harmonize airworthiness standards with our counterparts in Europe.

What I would like to do this morning is first provide a basic overview of the FAA's regulatory responsibilities with regard to airworthiness. Then I will focus most of my remarks on the FAA's bilateral agreements and harmonization program.

FAA Regulatory Responsibilities

By law, the FAA regulates the safe design, manufacture, maintenance and operation of aircraft flown in the U.S. aviation system. The term "airworthiness" generally applies to all these activities. In the manufacturing of aircraft specifically, the FAA ensures that an aeronautical product's design meets all applicable federal aviation regulations for its type -- for example, small helicopters, transport airplanes, engines and propellers. When a product is found to meet United States design standards, the FAA provides the manufacturer with a certificate or design approval.

The FAA also exercises oversight to ensure that U.S.-made aeronautical products are manufactured to production standards. Typically, this involves reviewing a manufacturer's quality control systems and production facilities. In this event, the FAA issues a production certificate. When an aircraft, engine or propeller is completed, the FAA must confirm that it conforms to the approved design and is in a safe condition for flight. If so, the FAA issues an airworthiness certificate for that product.

Once an aircraft is completed and delivered to its owner, the FAA then monitors the aircraft's continued operational safety. This is a top priority, given the size and age

of the U.S. aircraft fleet. The FAA watches for any service difficulties or trends that may require corrective action to an aircraft's design or procedures for handling. If any is needed, the FAA will issue an airworthiness directive requiring remedial action.

Finally, the FAA monitors the maintenance and operations of aircraft, as well as licenses pilots and registers aircraft. In particular, the FAA certifies repair stations and maintenance personnel that work on U.S.-registered aircraft. It also licenses and oversees the safe operation of U.S. air carriers.

The vast majority of the FAA's work is domestic. However, aviation is an inherently international enterprise. As a result, the FAA has developed methods for approving foreign products for use in the United States and for cooperating with foreign authorities to certify exported U.S. aeronautical products.

FAA Bilateral Agreements

Earlier in my remarks, I indicated the FAA takes a bilateral approach to regulatory cooperation in order to facilitate the import and export of civil aeronautical products. Since 1929, the FAA has developed a network of 27 bilateral airworthiness agreements (BAAs) that facilitate the reciprocal acceptance of certification work performed on aeronautical products by the airworthiness authority of the exporting country on behalf of its counterpart agency in the importing country. While most of these agreements are with European counterparts, the United States has BAAs with countries in all regions of the world.

There are no U.S. statutes or federal regulations that require a bilateral agreement to exist between the United States and a country exporting its aeronautical products to the U.S. Similarly, no other country requires these arrangements for the import of U.S. products, either. Nonetheless, the U.S. Government has entered into BAAs for reasons of safety and regulatory efficiency. Given its statutory safety mandate, the FAA must certify the airworthiness of products operated in the U.S. aviation system, whether manufactured domestically or overseas. It would be impractical and costly to place design engineers and inspectors at foreign facilities that export products to the United States. Instead, through bilateral airworthiness agreements, the FAA ensures that U.S. safety standards are satisfied through maximum use of the exporting country's certification system. Conversely, our foreign counterparts rely on the FAA's system with regard to U.S. products exported to their countries.

The U.S. Government enters into the agreements with those countries that have competent airworthiness authorities. The FAA determines such competency through detailed technical assessments of its counterparts' capabilities, national laws, regulations and certification systems. If the findings are favorable, the Department of

State negotiates the BAA, with FAA as its advisor.

BAAs vary in scope, depending upon the level of competency of the CAA and the level of aviation industry activity within that country. For example, some agreements cover only gliders and small airplanes, while others apply to the full range of aeronautical products, from components and appliances to transport aircraft.

The bilaterals provide for increased levels of cooperation between civil aviation authorities. For example, during the design-approval process for a transport aircraft, the importing authority will work closely with its exporting counterpart -- that is, the authority of the country of manufacture -- in order to become familiar with the aircraft and establish the importing country's certification basis. The importing authority will rely on the exporting authority's certification to its national standards and to any additional conditions the importing authority may outline in order to make up for differences with its standards. Under the BAAs, certificates are to be given "the same validity" by the importing state as if the importing state's airworthiness authority had performed the certification "in accordance with its own applicable laws, regulations, and requirements."

Last, BAAs provide for continued cooperation between authorities. The agreements' language requires the civil aviation agencies to inform each other of any unsafe conditions with regard to their respective products and to provide guidance on remedial action. Additionally, the authorities are required to update each other on any changes in their airworthiness regulations and procedures.

Despite the benefits gained through bilateral airworthiness agreements, they do have some drawbacks. First, they cover only aircraft certification. They do not address regulatory matters in the areas of aircraft repair and operations, for example. As U.S. air carriers increase their international route networks and operate more aircraft overseas, the FAA must follow by certifying foreign-based repair stations that wish to perform maintenance work on U.S.-registered aircraft. Moreover, the practices of code-sharing and leasing aircraft from one country to another have become more common and raise questions of operational oversight. Second, the BAAs are inflexible to the point that we have to resort to a diplomatic process for technical amendments. For reasons of efficiency, it would be desirable to be able to make such amendments without having to involve foreign ministries whose concerns reasonably lie elsewhere.

The bilateral aviation safety agreement (BASA) will address these drawbacks and provide for even greater regulatory cooperation between the FAA and competent overseas authorities. It is a new vehicle developed by the FAA and the Department of State in conjunction with our European counterparts. First, the BASA's scope will include coverage of repair station certification, maintenance personnel approvals, flight simulator evaluations and operational oversight, in addition to the aircraft certification coverage of current BAAs. Second, diplomatic involvement will be focused only on concluding the umbrella executive agreement that will outline the potential scope of the BASA, define certain terms, designate the civil aviation authorities, and provide

termination provisions.

Appended to the executive agreement will be the implementation procedures -- or IPs -- developed and negotiated by the civil aviation authorities. These represent the meat of the BASA, because the IPs will describe the detailed procedures for carrying out the activities that support the concept of greater regulatory cooperation under the agreement. A set of IPs could be developed for each of the technical disciplines I have mentioned. The authorities can also amend the IPs as needed. As with the current BAAs, the actual scope of each BASA will vary. Last month, we concluded the first BASA executive agreement with the Netherlands and expect to begin negotiations with the United Kingdom this summer.

FAA Harmonization Program

Another method through which the FAA is promoting high levels of safety in international aviation is our harmonization program with the Joint Aviation Authorities (JAA) of Europe. The JAA is essentially a club-like organization through which 23 European countries have sought to harmonize their national regulations. Although the national aviation authorities of the JAA member states still maintain legal responsibility for implementing and enforcing the European regulations, the JAA represents their unified views in harmonizing European standards with those of the United States.

FAA-JAA harmonization efforts began informally more than a decade ago. It has since become more formal and institutionalized as we have broadened the scope of requirements and practices to be harmonized. Initially, the FAA and JAA focused on aircraft certification matters. The current harmonization work program contains projects in both the aircraft maintenance and operations areas. The ultimate goal is to bring together, to the maximum extent possible, European and American airworthiness standards and procedures.

On an institutional level, the FAA and JAA hold annual plenary sessions with industry representatives to discuss progress and next steps. Moreover, both organizations have integrated into their respective rulemaking systems opportunities to take into account the views of the other. The process involves both civil aviation authorities and industry and provides for an FAA-JAA harmonization working group that effectively shepherds regulations through the rulemaking process. Technical working groups meet periodically to address specific matters and play a central role in this process.

In addition to harmonizing written standards, the FAA and the JAA must also harmonize their respective interpretations on implementation. The recent certification of the Boeing 777 provides an instructive example. In a presentation at the annual FAA-JAA meeting last June, the Boeing Company said that the 777 had to meet almost 1,250 safety requirements as part of a joint U.S.-European certification program. Eight hundred fifty regulations, or 68 percent, were considered fully harmonized in both text

and interpretation. Of the remaining 396 requirements, 169 represented regulations with the same text but different implementation interpretations, and the remainder were either U.S. regulations with no corresponding European regulations, or vice versa. Despite differences in 32 percent of the safety requirements, the cooperative certification program resulted in the simultaneous design approval of the 777 in the United States and 19 European countries. While we're proud of this accomplishment, we're still working to harmonize the remaining differences.

The FAA's bilateral arrangements and harmonization efforts play a significant role in how the FAA and other airworthiness authorities from around the world together will provide safety regulatory oversight in an increasingly global environment. They will allow us to use our limited resources more wisely through enhanced cooperation, improved understandings of accountability and similar standards and interpretations. As a result, we anticipate greater regulatory efficiencies. This means industry should subsequently enjoy the benefits of cost- and time-savings associated with reduced duplication of certification work. Most importantly, though, we believe that air transport users will benefit from a very high level of safety from country to country.

I would be pleased to answer any questions.

HELPING TO REDUCE TECHNICAL BARRIERS TO TRADE

Belinda L. Collins, Ph.D.
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Dramatic changes are occurring in the international markets that form the background for U.S. standards and conformity assessment activities. Last year the United States exported about $700 billion worth of goods and services. These goods and services were sold into an increasingly competitive global market containing many barriers to trade. Having a large domestic market, good quality and reasonable price are no longer guarantees of market access for a product. Technical barriers to trade (TBTs) almost always must be overcome or dealt with constructively to gain access to a market before any product can be traded. Trade experts have indicated that additional exports worth $20 to $40 billion could be produced right now if we could overcome all technical barriers to trade.

Most TBTs result from disparities in standards and conformity assessment practices between the United States and its trading partners. While some TBTs have legitimate purposes, such as the protection of human health and safety, the environment or national security, others have no legitimate purpose and exist only to protect domestic markets.

To provide a world-wide means of addressing technical barriers to trade, the Uruguay Round of trade talks created a new institution -- the World Trade Organization (WTO) -- as a successor to the General Agreement on Tariffs and Trade (GATT). The WTO will provide a single, coordinated mechanism to ensure full, effective implementation of a revitalized world trading system. The WTO requires full participation of all members in all aspects of the current GATT and Uruguay Round agreements and provides a permanent, comprehensive forum to address the new or evolving issues of the 21st century.

Unlike the GATT agreement, all those who sign the WTO agreement also are signatories to the Standards Code (now termed the TBT Agreement), increasing membership from about 46 to about 123. The new TBT Agreement, unlike the prior standards code, can be enforced through the full GATT dispute-settlement system process. It also allows the use of the unified WTO dispute-settlement system and permits withdrawal of concessions under any of the WTO agreements.

The Agreement on Technical Barriers to Trade is designed to eliminate the use of standards-related measures as barriers to trade. It establishes international rules by which governments can regulate procedures for preparing, adopting and applying standards-related measures. The agreement applies primarily to central governments that are, in turn, responsible for ensuring compliance by local government and non-

governmental bodies. It covers technical regulations and standards, conformity assessment procedures, information and assistance, transparency and information exchange.

The TBT Agreement defines technical regulations as product characteristics or related processes and production methods with which compliance is mandatory. Standards, however, are defined as documents approved by a recognized body that provide for common and repeated use of rules, guidelines or characteristics for which compliance is not mandatory. The term "standards" includes terminology, symbols, and packaging, marking or labeling requirements as applied to products, process and production methods.

The WTO Agreement emphasizes the use of international standards or relevant parts as a basis for technical regulations, except when ineffective or inappropriate. It encourages all members to participate in the preparation of international standards and promotes the development of performance, rather than design or descriptive, standards. The agreement stresses that technical regulations should not be prepared, adopted or applied to create unnecessary obstacles to trade.

In addition to standards activities, the TBT Agreement now directly addresses conformity assessment. It defines conformity assessment as any procedure used to determine that relevant requirements in technical regulations or standards have been met. These procedures include sampling, testing and inspection, evaluation, verification and assurance of conformity, and registration accreditation and approval. Any proposed changes in conformity assessment procedures also must be reported to other governments and must not be prepared, adopted or applied so as to create unnecessary obstacles to international trade.

The agreement encourages the use of relevant guides or recommendations by international standardizing bodies. Furthermore, WTO members are encouraged to negotiate mutual recognition agreements of the results of their conformity assessment procedures. Thus, conformity assessment bodies (such as laboratories and accreditors) are encouraged to participate in foreign conformity assessment procedures. The WTO also encourages bilateral and multilateral agreements between member counties on issues related to technical regulations, standards and conformity assessment procedures. Information to be made available includes processing of applications, fees, facility sites, complaint review procedures and confidentiality procedures.

Central to the TBT Agreement is information exchange. To facilitate this, the agreement provides for notification procedures that require central governments to report to WTO any proposed technical regulations that may significantly affect trade with other WTO members. These notifications are to be distributed to all WTO members for review and comment. In addition, central governments must report technical regulations proposed by local governments directly below the central

government, which means that the U.S. is obligated to report actions of the 50 U.S. state governments.

Central governments are also required to use a code of good practice for the preparation, adoption and application of standards. Governments must take "reasonable measures" to ensure that local governments and private standardizing bodies avoid duplication of, or overlap with, the work of other standardizing bodies and report their activities every six months. These activities are reported to the International Organization for Standardization (ISO) information center in Geneva, with NIST as the ISO information network (ISONET) contact for the United States.

The goals of the WTO focus on transparency and information exchange. Under the TBT Agreement, members must establish and maintain an inquiry point. Inquiry points are key to achieving transparency and exchanging information. They serve as focal points within each member for obtaining and exchanging information on technical regulations, standards and conformity assessment procedures. Each inquiry point also provides notifications about proposed technical regulations to the WTO secretariat. Each inquiry point answers requests from other members on technical regulations, standards and conformity assessment procedures, including providing information on where documents can be obtained.

Turning now to activities that NIST has undertaken to make the WTO goals a reality, let me describe a number of programs that support international trade and standards.

To fulfill the obligations under the WTO, NIST has established the National Center for Standards and Certification Information (NCSCI). NCSCI serves as the U.S. inquiry point and responds to requests about non-agricultural products, while USDA provides responses for agricultural product requests. As the inquiry point, NCSCI, along with all WTO members, provides technical assistance on standards and conformity assessment information. In 1993, for example, we provided notifications of more that 485 proposed foreign regulations and about 60 proposed U.S. regulations, while processing more than 9500 requests for standards-related information. Thus, inquiry-point assistance may include information on establishment of institutions to enable members to fulfill the obligations of membership or participation in international or regional systems for conformity assessment. Under the WTO agreement, NIST will fulfill the U.S. inquiry-point responsibilities (for GATT, NAFTA, and ISONET) and maintain a technical office (NCSCI) to assist exporters with information and standards-related trade issues.

As the United States increases its participation in the WTO, all federal regulatory agencies must consider their roles in standards, regulations and conformity assessment. As I mentioned earlier, NIST operates, and will continue to operate, the inquiry point under both the WTO and NAFTA agreements and is responsible for information exchange among governments relating to technical regulations, standards and conformity assessment. Clearly, NIST will continue its traditional role in the

development and maintenance of the technical infrastructure needed to support standards activities. We will continue to provide the fundamental measurements, standard reference materials, standard data, and calibrations needed by industry and government.

In addition, NIST is continuing its long history of participating in the private voluntary standards process and is committed to continue efforts towards its success. NIST currently has about 375 staff participating as technical experts in more than 820 voluntary standards committees in about 80 organizations, both national and international.

NIST participation as a government member in the American National Standards Institute (ANSI) has long been a priority. In fact, the National Bureau of Standards, our predecessor agency, worked with the major private sector standards developers to establish ANSI in 1919. Our technical participation in private sector standards activities and our record of cooperation with ANSI and private sector standards developers is valued by the private sector. As part of our continuing relationship with the private sector, NIST and ANSI hope to sign a memorandum of understanding (MOU) by mid-summer. We believe that this MOU will reflect the activities and responsibilities that both ANSI and NIST have to facilitate communication among all affected parties to make the standards system even more effective in the future. These responsibilities include ensuring continuing participation of federal agencies, such as the Consumer Product Safety Commission (CPSC), in the standards process.

To provide greater information about standards and conformity assessment activities, NIST is currently expanding its program of standards assistance in key emerging markets. The NIST trade support program will be patterned after the successful technical assistance program to Saudi Arabia that was authorized by Congress in 1989. In cooperation with the private sector, in 1990 NIST began the Saudi project, which reversed the trend by Saudi Arabia to embrace European standards and discourage import of products made to standards. Since 1990, imports to Saudi Arabia have increased significantly. As part of our FY 1995 initiative, we have placed another standards expert with the Foreign Commercial Service (FCS) in Brussels for the European Union and are preparing additional FCS experts for posts in Mexico City, Buenos Aires and New Delhi. These experts will coordinate closely with other federal agencies, ANSI, and interested industry and standards developing organizations.

NIST has also increased its efforts in education and information dissemination, with training courses now provided for experts in standards and metrology (fundamental measurements) from Russia, the newly independent states (NIS), India, the Caribbean, Central and South America. Just this week we are conducting a one-week training seminar on standards information (and operation of inquiry points) for developing countries, in conjunction with ISO. To date in 1995, we have already conducted three

two-week training sessions at NIST aimed at Russia, NIS and India. Each training session includes representatives from the private sector and from other government agencies, depending on the target sector. The experts from Russia and the NIS also spend six weeks in the private sector with key industries. This training provides them with first-hand insight into industry's role in standards and conformity assessment and, in turn, provides us with key contacts and information about standards related activities in Russia and the NIS.

A major result of these training efforts is greater adoption of technology, standards and conformity assessment practices, which greatly enhances our competitive advantage in the global marketplace and reduces technical barriers to trade worldwide.

After the first session, which was targeted at the automotive sector, participants from both industry and Russia and the NIS expressed overall satisfaction with the program and pleasure with the opportunity to make high-level contacts to facilitate future joint trading efforts. In addition, one auto company was able to facilitate Russian approval of two vehicle models that had been held up due to misunderstandings about conformity assessment procedures, misunderstandings that were cleared up during the training. In another training session, which focused on medical equipment, training again led to understanding of conformity assessment procedures for dental products and permission for specific products to enter Russia.

Other current educational efforts at NIST include training in metrology and standards activities at several locations in Latin America. Our key handbooks in weights and measures, as well as laboratory accreditation, are being translated into Spanish to assist NAFTA and hemispheric initiatives. NIST is also working with ANSI to develop the National Standards Systems Network (NSSN), which will eventually provide on-line access to standards and conformity assessment information. This project, which is co-funded under the Technology Reinvestment Project, should speed the flow of information about standards and conformity assessment and may eventually facilitate the development of standards with on-line authoring capabilities.

In addition, NIST chairs the Interagency Committee on Standards Policy (ICSP) for the Secretary of Commerce. The ICSP is made up of senior standards officials from federal agencies concerned with standards. It is charged with coordinating federal efforts on standards and overseeing the mandate given by OMB Circular A-119 -- to move from federal regulations to voluntary standards to the extent possible. This committee has a number of policy task groups active in areas such as ISO 9000, laboratory accreditation, policy and database information. It affords federal agencies the opportunity to share information and coordinate activities in standards and conformity assessment.

With ANSI and ACIL (the association of independent scientific, engineering and testing firms), NIST is sponsoring an informal working group on laboratory accreditation (LAWG) designed to explore problems in laboratory accreditation and bring all affected

parties together to develop more workable solutions. LAWG participants include other federal agencies, state agencies, accreditors, manufacturers and laboratories, all working together to define the issues and work toward solutions to reduce the problems of multiple, duplicate accreditation. Some laboratories report, for example, that they must undergo as many as 25 accreditations by different authorities, ranging from federal agencies to individual states, localities and manufacturers, with no reciprocity among them.

Recommendations

1. Turning to concerns that face all federal agencies, including NIST and CPSC, as we work to implement the WTO Agreement, there are a number of points to consider as we plan future activities. As a member of the ICSP, CPSC should consider participating in task groups to define federal regulatory activities in support of international standardization activities and the WTO. A task group could easily be established to explore such issues on a continuing basis. I would welcome participation by CPSC and other regulatory agencies in this group.

2. All federal agencies should continue to take advantage of the services of the NIST inquiry point in NCSCI to follow and respond to activities in other governments, as well as to provide them with proposed changes in regulations and standards. Use of the inquiry point will lead to more timely and effective information exchange among trading partners -- for consumer products, or, indeed, any product. Under the NIST Standards in Trade program, agencies can work with the standards experts posted to foreign countries to learn more about specific regulatory and trade issues and then work to resolve them. Finally, once the National Standards Systems Network, now being developed under ANSI and NIST sponsorship, comes on-line, CPSC and all agencies will have electronic access to the latest developments in standards and conformity assessment and may even be able to participate in the development of international standards without ever leaving their desks.

3. All federal agencies need to work together so that the federal government can speak with a single voice in the international arena. Together, we can make the dream of open markets that meet the health, safety and environmental needs of consumers become a reality.

NETWORKING: CPSC AT THE NET

Douglas L. Noble
Assistant Executive Director, Office of Information Services
U.S. Consumer Product Safety Commission

It is a pleasure to be with you today and briefly share a success story about CPSC'S networking efforts to improve the flow of important safety information to and from consumers. It is our hope that our experience can be used as a model for efforts to harmonize international standards through improved communications.

Our story centers around the agency's toll-free consumer Hotline. CPSC Hotline plays a pivotal role in fulfilling the agency's mission to reduce the unreasonable risk of injury from consumer products. It does this by providing consumers with vital product safety information, including information on product recalls. This information is available 24 hours a day, seven days a week through a menu of more than 300 recorded messages that callers can access by following a series of prompts when they call the Hotline.

The Hotline also is an important information-gathering tool for the Commission via consumers who call to tell us about injuries and deaths associated with consumer products. During regular business hours, callers can speak to Hotline representatives, in English or Spanish, to report product safety hazards. After business hours, callers can leave messages and are contacted the next business day by a Hotline representative to obtain a detailed report.

Shortly after Chairman Brown arrived at CPSC in March of last year, she held two back-to-back news conferences in one week. There was such a huge consumer response, in terms of callers seeking information through the Hotline, representatives of the federal telecommunications service contacted us to tell us that the numbers of calls to CPSC was threatening to bring down the federal 800 service along the entire Atlantic seaboard.

This crisis prompted us to improve, or "reengineer," our Hotline operations. In the first 12 months after the Hotline was reengineered, there was a 78 percent increase in the number of calls handled, compared to the previous 12-month period. After reengineering the Hotline, there were nearly 4,000 complaints about potentially unsafe products taken over the Hotline, compared to approximately 2,000 complaints during the previous comparable period.

To complement the improved communications via the Hotline, the agency established a fax-on-demand system that permits anyone calling from the handset of a fax machine to receive a hard-copy version of CPSC recall announcements and product safety advisories. In addition, the agency established two Internet services for

consumers. The first is a "listserv" subscription service for anyone wanting to receive press releases as they are issued by CPSC. The second is a "gopher" service where users can specify what information they wish either to see on-line or to download to their computers. International callers can obtain CPSC safety information on a toll-call basis via the Hotline and fax-on-demand services.

Our experience in reengineering the Hotline has all taken place in the context of Chairman Brown's response to the challenge to all federal agencies issued by Vice President Gore and the National Performance Review to carry out their missions more effectively through the use of information technology.

CPSC's success in meeting this challenge has been widely acknowledged. The Vice President recently awarded his "hammer award" to the Commission for the reengineering of its consumer Hotline. In addition, the agency was also chosen as a semi-finalist in the Innovations in American Government Awards Program jointly sponsored by the Ford Foundation and the Kennedy School of Government at Harvard University.

We regard the success we have achieved in our Hotline as part of our continuing effort to improve our ability to provide information on product safety to the nation's consumers. It is important to emphasize that this information is available internationally as well.

In closing, I want to stress that CPSC regards the availability of product safety information as something that need not stop at our nation's borders. Everyone recognizes that in the world marketplace, product safety problems are similar in many respects. As more information on these problems and their solutions is shared internationally, it reinforces efforts to harmonize product standards among nations. I hope this example of how CPSC has taken steps in the direction of making product safety information more widely available can serve as a model for future efforts to share such information internationally.

Thank you for letting me share this CPSC success story with you today.

PANEL III

PLAYING FROM THE SAME DECK:
THE BUSINESS END OF STANDARDS HARMONIZATION

Moderator: Howard Seltzer, Director for Policy and Intergovernmental Relations, U.S. Office of Consumer Affairs

Panelists: Gary W. Kushnier, American National Standards Institute (ANSI)

Mary Anne Lawler, IBM Corporation

Richard J. Schulte, International Approval Services

David A. Miller, Toy Manufacturers of America, Inc.

Mark Silbergeld, Consumers Union

CREATING INTERNATIONAL STANDARDS: ISO & IEC

Gary W. Kushnier
Vice President, International Policy
American National Standards Institute (ANSI)

Good afternoon. I would like to thank the Commission for inviting me to this important conference, which is most timely in this age of increasing globalization of standards.

As the American National Standards Institute's representative in Brussels from 1993-1995, I had direct access to officials at the European Committee for Standardization, the European Committee for Electrotechnical Standardization, the European Telecommunications Standards Institute, as well as applicable sections of the European Commission. I also had regular contacts with U.S. government officials at the U.S. mission to the European Union. Though now located at ANSI's New York office, I continue to maintain close relations with these organizations via visits to Brussels and frequent communications. My activities also involve participation at the policy level at the International Organization for Standardization (ISO).

In promoting U.S. standardization interests globally, ANSI is the U.S. member to the ISO and, through the U.S. National Committee, to the International Electrotechnical Commission (IEC). By having a high level of participation at both the policy and technical levels, ANSI is a prime mover towards the harmonization of national standards and international standards, either by direct use by individual sectors or by actual adoption.

Having globally agreed-to international standards helps facilitate free trade. ANSI's goal is to have global standards that reflect U.S. interests. We do this by having U.S. standards adopted abroad, by having U.S. positions on policy and technical matters accepted in international and regional standards development fora, and by having international standards adopted as national standards when they meet the of the user community.

ANSI promotes U.S. standardization interests globally as the U.S. dues-paying member to the ISO and, through the U.S. national committee, to the International Electrotechnical Commission. By having a high level of participation at both the technical and policy levels, ANSI is a prime mover towards the harmonization of national and international standards, either by direct use by individual sectors or by actual adoption.

The International Organization for Standardization is based in Geneva, Switzerland, and currently has 113 member nations. ANSI is one of five permanent ISO council members and one of 12 members of the ISO technical management board. We

participate with our members in 73 percent of the ISO technical committees and administer 14 percent of technical committee secretariats that are responsible for 44 percent of total standards pages.

ANSI accredits U.S. technical advisory groups (TAGs), which allows affected parties to participate in ISO standardization activities. U.S. TAGs provide for due process, openness and consensus, and ensure sufficient of affected parties. ANSI also ensures that the TAGs have adequate administrative support, which is provided directly by the Institute's members in nearly all cases.

ANSI participates actively in the International Electrotechnical Commission, also based in Geneva, through the U.S. National Committee (USNC) of that organization. There are currently 49 national bodies of the IEC. The USNC is a member of the IEC Council and one of 12 members on IEC's Committee of Action. We participate in 89 percent of the technical committees and are assigned 16 percent of the technical committee secretariats.

ANSI also plays an active role in regional policy fora, such as the Pan American Standards Commission and the Pacific Area Standards Congress. With the assistance of these regional fora, the Institute is able to pursue its international goals with additional support.

My recommendations to the Commission include being a more active participant on U.S. TAGs related to consumer activities and continuing active participation on the ANSI Consumer Interest Council and the ISO Committee on Consumer Policy. Participation is the name of the game, and the earlier in the process the better.

Thank you for your attention.

INTERNATIONAL STANDARDS OR PERISH

Mary Anne Lawler
Chairman, ISO/IEC Joint Technical Committee 1
Director, Standards Relations, IBM Corporation

I would like to thank the Consumer Product Safety Commission for the invitation to speak today. It's a pleasure for me, because normally when I have an opportunity to speak, I know 50 percent of the people in the audience who have heard the whole story before. So, it's especially nice to be able to tell my story to a new audience.

International standards really are key to the continued enhancement of the U.S. market. Everywhere we turn, we see that the marketplace is becoming increasingly global, either through trade agreements or in market demand itself. You know, ten years ago when you traveled in Europe, you went to each country and looked for special goods you only could get in that county -- perhaps wooden toys in Germany, fashions in France. Today when you travel through Europe, you find the same things everyplace, and you can even find those specialties here in the U.S. That's a pretty good indication that the market is getting global. With this internationalization of trade, international standards become even more important. Regional and national standards tend to decrease as the market grows.

Before I talk about the international standards activities, I'd like to take a look at why people participate in the international process. It's not cheap, it's timeconsuming, and to be effective, you have to spend time doing your homework and preparing contributions. It's a lot of work and effort. But from a manufacturer's standpoint, we feel it's well worth the time and effort. It provides open access to more markets. It gives us a world market that we did not have without international standards. It reduces development time. When you can produce one product that can be sold throughout the world without individual country requirements, certainly you reduce your product development time and you reduce your time to market. Once that product is produced, you can move it throughout the world. This becomes effective too, in breaking down trade barriers, because those countries that insist on maintaining some degree of trade barrier receive a product later and therefore may put both its industry and consumer public at a disadvantage.

Manufacturers also feel that participation in international standards activities is worthwhile, because you do begin to understand the world market requirements. You generally tend to know the market requirements in your native land, but they may not be the same as those in the Far East or Europe. Participating at the international level in the development of the standards, you see the requirements coming in from the various countries, so you do get a heads-up on what the marketplace is turning towards.

The other thing international standards provide is the ability to have one-stop testing. By one-stop testing I mean conformity of specimen routines are required. You can do your test once, and hopefully, through mutual recognition agreements, as well as industry agreements, that test will suffice around the world. So, you are reducing your costs and increasing your access to markets.

Why would an end user want to participate in an international process? Well, first of all, the users are interested in getting the best price performance they can. International standards help develop products that make available the best price performance on the market. And what is an end user? Is the end user a consumer? Is the end user a user of the standard? Is an end user government? Is the end user business? I maintain an end user is all of the above.

Now let me turn to the question of international standards in the information technology area. Information technology, either because it is a young industry or because it has rapidly developing technology, has always geared itself to the international arena. Back in the early 1980s, the industry said it did not have the time, the way technology is changing, to develop national standards and promote them into the international arena. What we must do for the marketplace is to take advantage of the technology, make the standards relevant by developing them in the international marketplace, then let countries adopt them as national standards should they so desire.

Implementation of international standards gives you the idea of the features that you want without having to pay for the features that you don't want. It allows for "interoperability," a term that's very much in vogue now. Particularly in the information technology industry, interoperability implicitly means you can put any manufacturer's equipment together with any manufacturer's software. You are not tied in to one manufacturer for your entire system -- your printer, your CPU, your keyboard and your software. With interoperability based on international standards, you can mix and match to achieve the system that's tailored to you. The end user also wants quality, and quality, we believe, is one of the main aims of international standards. The other advantage is with conformity assessment. The end user can be assured that if a product declares its conformity to international standards, that function is there.

I would say the work today in information technology standardization is done 95 percent in the international arena and then brought back to the national bodies. This is not to say that national requirements and contributions are not developed; they are very much developed in the national bodies and then taken to the international arena for implementation.

In the mid-1980s, the information technology industry, particularly led by the United States, said we need a different format because we've got committees in the IAC and in the ISO. So, we're duplicating efforts and resources, and that's costing time to develop standards. We need a new organization just for information technology. And lo and behold, the IAC and ISO agreed they would jointly sponsor a committee, known as the

Joint Technical Committee One (JTC1), whose responsibility is standardization in the field of information technology.

Today the JTC1 (of which I am Chairman) is almost eight years old. We have more than 1300 projects at some level of standardization, either at the working level, the draft level or the final international standards level. We also have projects putting together what are known as international standardized profiles. This takes groups of standards and ensures that they interact together to give a full system, a full local area network, if you will.

Within JTC1, we have thousands of people working within 19 subcommittees dealing in topics that vary from vocabulary to open systems, communications and multimedia. Many of you may have heard of the Impact 2 standard that came out of JTC1 and is now the standard for multimedia coating used by the movie, TV and programming industries. We have interchangeable storage media. We deal with document processing, electronic document interchange and a variety of other topics.

We currently have 32 participating members. These are member countries that vote, attend and participate actively in the meetings. I would say in the last couple of years we have had a great growth in membership. Particularly from the former Eastern bloc, we now have very active participation from the Russian federation, Estonia, the Czech Republic, Slovenia, Slovakia and all of Poland. All of them are becoming quite active. We also have 28 observer members. They do not vote but may comment and do get all documentation.

One of the things that the formal standards process is criticized for is taking too long. This really is not necessarily true. The process can be as rapid as the individuals involved would like it to be. The JCT1, by the way, has its own rules that are similar to those of the ISO and the IAC, although they are somewhat different. In the last two years, we have taken steps to shorten the time to develop standards. We were averaging just under three years from start to finish. Since we changed our procedures, we shortened that by a good six months, beginning the middle of this year.

As they say, the shoemaker's children are the last to use the technology. The JTC1 was criticized for not using the information technology within its development work. So, at the plenary level this year, we finally began automating our process. The actual subcommittees and technical work groups have also begun automating their process and do a great deal of development and commenting on-line. It used to be that my phone messages and my "snail-mail," as they call it, were a mile high. Now it's my e-mail I can't get through.

The other thing that JCT1 felt it had to do related to a rapidly changing world and business environment, particularly in information technology, where we have seen a lot of company reengineering, cutbacks and new ways of doing things. We realized we'd better look at ourselves and make sure we were running as a business and taking

advantage of those valuable resources that companies, governments and users were giving up. Last month we began a business analysis of JCT1 to articulate the JCT1 role, just as you would a business role. We are identifying our products, services, customers and suppliers and defining a success matrix. Our analysis will be completed the beginning of 1996.

For years the measure of success in standardization was the number of pages you produced: the more pages, the greater the success. It did not matter if anyone implemented your standards, but if you had those stacks of pages, you were great. We maintain that's not necessarily the case today. We are looking at what the critical success factors for international standards are. Are they quality? Are they timeliness? Are they efficiency? Are they relevant? How much quality will you sacrifice for timeliness? Sometimes you can take five years to develop a perfect standard, but you can have a 97 percent perfect standard in the three markets you would use.

Another thing that we have found recently is that it's very important that our work be harmonized with the work of other organizations. We have some degree of overlap with the International Telecommunications Union, and over the last several years we developed a close relationship with the ITU. We have a collaborative work program with them where work is predominantly done in either one organization or the other, or jointly by the two groups. We process the work jointly so that in the end we will not confuse the consumer. We hope we can come up with one standard that's the same in the voluntary census arena of JCT1 as in the ITU recommendations.

We also have begun a dialog with the Internet Society. The Internet Society currently has a liaison relationship with several of JCT1's subcommittees, and we are looking to develop some type of working collaborative procedure we can utilize with them. That is currently underway.

We recognize that the standards committee can't do all the work. We also recognize that there are things out there such as de facto standards and specifications being developed by non-standardizing organizations and consortia, but very valid specifications nonetheless. So, just six months ago, JCT1 approved a procedure whereby we could go outside the standards process but keep our criteria and some degree of control. For example, in the intellectual property rights area, we can bring in publicly available specifications, or de facto standards, and formally process them through the international arena to international standards, with the national body still retaining its vote. We believe that in six to seven months, we can

take an outside specification, bring it in the formal process, get international agreement on that specification and publish it as an international standard.

We feel this is a breakthrough. Using this new procedure gives us flexibility. We don't have to do all the development ourselves, it should enhance our speed, and it gives us some degree of assurance that we are meeting marketing requirements and market demands because that is what we are there for. We are in a trial period that will last until January 1997, and I am looking forward to the success of that. We have put procedures into place that will allow us to reference specifications within our standards from outside the process.

I would like to touch on two more things. The first thing became very evident within the last two years. That was the fact that not just within the U.S. but around the world, nations were developing their own national information infrastructures (NII). The U.S. has its NII effort going, Canada has its Canadian highway effort, Korea has an effort, Japan has an effort, the European Union has an effort, and some of the countries in the European union have their own NII efforts. We have got to make sure that when they are completed, they all fit together so we do truly have a global information infrastructure (GII).

The second thing relates to JCT1's role in a global information infrastructure, whose intent is to improve trade, employment and education. Last October, JCT1 discussed its role. We said we are a very key element of the global information infrastructure from a standardization viewpoint, but we are not the only element. We went to the ISO, the ISEC and the ISTU and said you have a major role to play, and we feel we have a role to play. We proposed an international workshop to ensure that international standards is the overriding factor that is being used for the backbone, or at least the nucleus, of the information infrastructure, as far as the technology goes. So, with the permission of those three organizations, we have begun an intensive GII program organization plan. There will be an international GII seminar sponsored by the ISO, IEU and ITU next January in Geneva. JCT1 has also established its own group to deal with the overview and monitoring GII standards.

Let me conclude with some recommendations, which echo some that have already been made.

The key to maintaining U.S. leadership is participation in the standards development process, especially at the very earliest stages, to ensure that U.S. requirements are considered. It's almost impossible, once positions are set and countries have dug in, to change anything. If you don't participate early in the process, you are just a lone voice in the wind. People look at you and ask, "Why weren't you at the table? We had that discussion six months ago. If you cared, you would have been here." So, the key is participation. Do it early. Do your homework. Come with papers and contributions. Don't just come and think you can talk through a subject. The people who are winners are the people who lay their positions on the table early. Be

politic. Do your diplomatic coffee breaks. Get some allies.

Participation in the standards-development process can be costly, but in the long run, it saves money. You get your product out there faster. You have more markets. And, you can be assured that more products developed by other nations are going to meet your requirements when they meet international standards that you participated in developing.

Thank you very much.

THE U.S.-CANADIAN HARMONIZATION EXPERIENCE IN THE GAS SECTOR

Richard J. Schulte
President & CEO
International Approval Services

In the U.S. and Canada, 60 million customers purchase natural and propane gases from local distribution companies. Those gases are used to fuel about 200 million appliances that provide space heating, hot water, cooking and other services for residential and commercial customers. It is my purpose here to provide you with a brief overview of the joint U.S.-Canadian standards and certification programs for gas appliances.

The U.S.-Canadian Delivery System for Natural and Propane Gases

The gas delivery system in the United States is comprised of exploration and production companies, firms providing gas transmission and storage services, gas brokers and marketers and local gas distribution companies. A related group of manufacturers, distributors and contractors provide the pipe, cylinders, valves, compressors, controls, meters and construction services needed to install, operate and maintain the delivery systems for natural gas and propane.

At the end of the delivery system are gas customers identified as residential, commercial or industrial end users. Gas-fired furnaces, boilers, water heaters, cooking appliances, room heaters and other utilization equipment are supplied to gas customers by another group of manufacturers, distributors and installation companies.

Operation of the gas industry in the U.S. is regulated by federal, state, municipal and private-sector organizations. Regulation of safety for gas appliances used by residential and commercial customers is primarily conducted in the private sector through development of consensus standards and use of voluntary certification programs.

The gas delivery system used in Canada is similar to and interlinked with the U.S. delivery system described above. A common base of manufacturers provides similar equipment to gas suppliers and nearly identical appliances to gas consumers, in both countries. As a consequence, over the past ten years Canada and the U.S. have created coordinated processes for developing gas appliance standards and certifying gas-fired products for safety. These processes are now so closely joined that it is no longer possible to describe the U.S. standards and certification programs for gas products as separate from those of Canada. The binational programs are also multi-fuel in that they provide testing criteria and certification services for gas appliances fueled by either natural or propane gases.

Our broad objective is to make this hemisphere a very safe and friendly place for the production, delivery, trading, marketing and use of natural and propane gases, gas appliances and the equipment used in producing and delivering these clean fuels.

U.S.-Canadian Standards Program for Gas Appliances

The U.S. standards program for gas-fired appliances and controls is about 70 years old. It is conducted under the supervision of three national standards committees accredited by the American National Standards Institute. The committees, in turn, delegate technical work to subcommittees of technical experts representing manufacturers, local distribution companies and governmental agencies. The Canadian gas industry has had a similar structure for development and maintenance of its safety standards. The Canadian system operates under the supervision of the Standards Council of Canada.

Starting in about 1986, the gas industries in Canada and the U.S. took steps to consolidate their respective families of safety standards for gas appliances into harmonized standards acceptable for use throughout Canada and the U.S. U.S.-Canadian working groups and U.S. standards subcommittees, which formerly operated as independent bodies, were restructured into joint technical subcommittees. They are charged with creating, insofar as possible, one list of harmonized appliance standards that can serve both the Canadian and U.S. gas markets and are implementing the binational standards development process.

Our goal is to achieve full harmonization of existing U.S. and Canadian standards by December 31, 1996. We are well on the way to meeting that goal.

The U.S. and Canadian gas industries also have a longer-term objective: to foster the development of regional standards for gas appliances and utility equipment of common design that can be marketed in North, Central and South America. Such regional standards covering the U.S., Canada, Mexico and the MERCOSUR trading area, for example, could substantially reduce existing technical barriers to trade within the hemisphere.

The U.S.-Canadian Certification Program for Gas Appliances

Until about 1986, the U.S. operated an independent national testing program for gas appliances and related gas control equipment. A similar and independent program was operated in Canada. After 1986, Canada and the U.S. took steps to coordinate their respective testing programs to remove both delays and duplicate testing requirements from the private sector approvals systems operated by the American Gas Association (AGA) and Canadian Gas Association (CGA).

In 1993, AGA and CGA formed a joint venture -- International Approval Services (IAS) -- to provide standards, certification, quality system registration and field safety

testing services for gas equipment destined for sale in Canada, the U.S. or both countries. Any one of three IAS laboratories and four IAS engineering service centers can issue both AGA and CGA certificates without imposing duplicative testing or administrative costs on manufacturers.

IAS, AGA and CGA have adopted the business philosophy that it should be possible for many gas appliances to be tested one time, at one place, and achieve certification supporting sale anywhere on a global basis. The adoption and use of international standards would greatly facilitate application of this philosophy. We have found, however, that it is possible to bridge differences in gas product standards and operate a worldwide certification service through an array of exchange agreements with other certification bodies in Europe, Asia, Mexico and South America. Through these agreements, IAS is able to exchange appliance test data, factory inspection assignments and quality system (ISO 9000) registration certificates.

In both standards development and gas appliance certification, the U.S. gas industry and its Canadian counterpart are focused on two important objectives: first, to maintain and promote a high level of safety for gas consumers in the design, production, installation, fueling and use of gas-fired appliances for residential and commercial applications; and second, to pursue, as a long-term vision, the philosophy that it should be possible for a gas appliance or accessory to be tested one time, in one place, and be certified for sale, installation and use anywhere on a regional or global basis.

We are actively working with counterpart agencies worldwide that have a similar vision and consistent business objectives.

Recommendations

The U.S. gas industry and CPSC have a long history of coordinated action when it comes to maintaining safety for gas consumers and the public at large. In our new world of harmonized standards and certification procedures, we look forward to the further evolution and improvement of this relationship. We hope that CPSC will do the following:

1. Continue to rely on voluntary standards in fulfilling its regulatory role over gas products used in the residential markets;

2. Find sufficient resources to have its staff continue their participation in the deliberations of the gas industry's voluntary standards committees;

3. Establish working relationships with counterpart regulatory bodies in other countries so field problems found with gas appliances in international trade can be identified and corrected on a coordinated basis; and

4. Prepare itself to deal with future safety problems, which we anticipate will be more system-related than product-based. The gas industry is rapidly recognizing that alleged field problems with gas appliances are more and more frequently a product of overall building designs, installation methods, incorrect maintenance procedures and weaknesses in consumer education programs.

We look forward to working with CPSC in all of these areas.

TOYING WITH SUCCESS: MAKING MARKETS MANAGEABLE

David A. Miller
President
Toy Manufacturers of America, Inc.

I would like to thank the Consumer Product Safety Commission (CPSC) for inviting the toy industry to participate in this important conference. Along with a sizeable number of other industries, the U.S. toy industry, through its subsidiaries and distributors, is a major factor in virtually every country in the world that observes the rules of the World Trade Organization. Moreover, most TMA member companies, whether large or small, make and sell their products worldwide. Accordingly, all have the same problems and opportunities when doing business abroad.

I hope it will be helpful to you if I tell you briefly how we are regulated here in the United States, how we are regulated in the major markets around the world, what we are doing to harmonize standards, and finally, what we think the U.S. Government can do to help the toy industry and other U.S. consumer products industries compete effectively around the world.

How Are We Regulated?

Mandatory toy safety regulations are made by CPSC based upon the provisions of the Consumer Product Safety Act and the Hazardous Substances Act. In addition, the industry is guided by voluntary standards originally created under the National Bureau of Standards and then transferred to ASTM and designated F963. As you would imagine, the mandatory standards relate to life-threatening hazards, such as small parts and lead in paint.

It is incontrovertible that the mandatory federal standards, together with ASTM F963, represent the only, and I repeat, only standard in the world based upon meaningful injury data and universally recognized hazard analysis mandates. Supporting our U.S. standards is the only known comprehensive anthropometric studies of the size, shape and strength of children, which were conducted by the University of Michigan beginning in the late 1960s.

While there are hazards at the fringes that should be dealt with, it is fair to say that we have had in the United States the most comprehensive toy safety standards in the world for at least the last 20 years. Parenthetically, the United States is the only country with uniform, effective and fair enforcement of its regulations. Yes, I said "fair."

The toy industry is not alone. Many U.S. consumer product industries lead, if not

dominate, world markets. Most have had either voluntary or mandatory standards.

Where Are We Now?

In the past, when a U.S. company encountered significant impediments to doing business abroad, the usual reaction was to shrug and say "maybe another day" and go back to expanding the U.S. market. However, today in many consumer product industries, and toys lead the way, international growth offers greater opportunity than further expanding markets in the United States. Accordingly, we no longer have the luxury of ignoring foreign regulation, over-regulation or barriers to trade, be they in the areas of market access, product standards or restrictions on reasonable ways to do business. Free and open markets are the only road to growth for my members, whether they are large or small.

Are consumers in foreign countries entitled to the same protection we give consumers in the United States? Absolutely! And in a perfect world, the standards for safety and consumer protection should be the same.

Well, how are we doing in this less-than-perfect world? Let me take you for a quick trip.

Let's cross the Atlantic to Brussels and to the European Union (EU), which today is made up of 15 countries with a combined population of 350 million. When retailers are free to function cross-border in these countries, it will be the second largest market for toys in the world. Product standards are set in Europe by the European Commission issuing directives to the European standards-setting body, whose acronym is CEN. It is made up of the standards-setting national organizations of each EU member, such as the British Standards Institute.

Toys was one of the first "new directives" issued by CEN in the late 1980s, with a mandate that toys were to comply with a European standard, EN-71, by January 1, 1990. Accordingly, toys were one of the first consumer product industries regulated in the European Union. However, it is the standard setting process that concerns us. It is neither transparent nor does it offer an opportunity for affected non-European organizations to voice comments about proposed standards and have their comments dealt with substantively. Contrast this, if you will, with CPSC rulemaking procedures, as well as the standards processes under both ASTM and the American National Standards Institute (ANSI).

We are able to peek into the European standards process through the subsidiary companies of some of TMA's members. The chairman of the CEN technical committee on toys exercised his discretion and allowed one of our members to sit in on some of the standards meetings as an International Organization for Standardization (ISO) observer. What did we see? Standards-setting sometimes made by unsupported anecdotal evidence, use of experts "intellectualizing" risks, and very

little regard for injury data or demonstrations that regulations will, in fact, reduce injuries. It often turns into a battle between technically competent but politically motivated consumer representatives from small northern countries pitted against technically competent but politically naive industry representatives. Guess who wins? There are absolutely none of the risk-assessment requirements binding the deliberations of CEN that we take for granted when functioning either on a U.S. Government-mandated or voluntary standard-setting exercise.

Add to this frustration the "Vienna Agreement," an agreement between CEN and the ISO. Under this agreement, a standard agreed in Europe is automatically transferred up to ISO for ballot. So we are faced here in the United States with circumstances under which we have no direct impact on the drafting of a standard and then are forced in the international body of ISO to vote up or down on a standard set in the dark.

Let's depart beautiful Brussels and fly east to Beijing. Today, China produces close to 50 percent of all the toys consumed in the world, and it represents at least 40 percent of all U.S. toy consumption. Under its toy export quality licensing laws, a product must be produced under either European or U.S. safety standards to qualify for an export license. Domestically, and China has just started to become a toy-consuming country, it is regulated by the old European standard, EN-71.

However, we are in close contact with both the domestic and international regulatory bodies in China, and they demonstrate typical Chinese pragmatism. Accordingly, we foresee little difficulty in China adjusting to either harmonized standards or mutual recognition agreements, or, should lightning strike, a uniform world toy safety standard.

Now let us travel further east across the Yellow Sea to Tokyo. Until June 30 of this year, there was no product liability law protection for Japanese consumers, short of being able to prove manufacturer negligence. However, all of that has changed with the enactment of a product liability law similar to those in the United States. I suspect that our diligent Japanese friends will soon have meaningful injury data and will revise their adequate but less-than-complete toy safety regulations to more closely mirror our own.

While we are crossing the Pacific back to North America, let me tell you about two other standards processes in which we are involved. First, as you have heard, toys are one of the categories that is targeted for mutual recognition agreements between the Pacific Rim countries. We enthusiastically support this effort through the Asia-Pacific Economic Cooperation forum and have worked closely with Suzanne Troje of the Office of the U.S. Trade Representative. Second, at the invitation of CPSC, TMA became involved in a project of the Organisation for Economic Co-operation and Development and its Division of Competition and Consumer Policy. It is a project to determine whether safety standards, including toys, are being used as

barriers to trade.

We now arrive in Ottawa. As on most issues, we are in substantial agreement with our Canadian friends. There are five differences of significance between U.S. toy safety standards and those of Canada. However, there is a memorandum of understanding between the United States and Canada to harmonize product safety standards, including toys, and we are hopeful that CPSC will actively pursue such harmonization with Canada.

Let"s turn now to the three NAFTA countries and the trilateral initiative to harmonize voluntary standards among the United States, Mexico and Canada. Because both U.S. and Canadian standards are hybrids with voluntary and mandatory components, this is really a nine-sided discussion among the voluntary standards organizations of each country, their government representatives and the private sector. We have been studiously working at this process for the last three and one-half years and are close to getting Mexico to adopt a harmonized U.S.-Canadian standard.

Unfortunately, the combination of the change in government in Mexico, together with a concern by the Mexican Government that it could not enforce the harmonized standard, led to the withdrawal of a published standard prior to its second reading. We are once again on track and hope we will see the Mexican Government adopt this harmonized standard within the next year. The motivation for the U.S. toy industry is substantial.

First, it will allow for the free movement of toy products between our countries. There are economic benefits for manufacturers in all three NAFTA countries. In addition, it will make it easier for large U.S. retailers like Wal-Mart, K-Mart and Toys "R" Us to do business economically and efficiently under NAFTA.

Second, because Mexico is one of the two leaders in Latin America, along with Brazil, a Mexican toy safety standard harmonized with the U.S. and Canada has a good chance of being adopted in the rest of the Americas.

Where Are We Headed?

Now that I have demonstrated that my job is not in jeopardy for lack of work, let us look at where are we headed.

First, we have mounted a worldwide effort in ISO to vote down the ill-considered European standard on mechanical and physical hazards. This is not easy, in view of the fact that Europe starts with 15 votes. Isn't it funny that they want to be treated as a single market with 350 million people but insist upon 15 votes in standards-setting when the United States gets one and China, with 1.2 billion, people also gets only one vote.

Second, we have completed a draft international toy safety standard based upon

U.S. mandatory standards and ASTM F963, which we will propose through ANSI to the ISO. We will then attempt to persuade the standards-setting bodies in each voting ISO country that acceptance of this standard is in the best interest of their own country, as well as the world.

Third, we will continue to actively work within the trilateral standards-setting process now taking place among Mexico, Canada and the United States. The three toy associations are in sync. There is significant cooperative dialogue between the standards-setting bodies. It is now a matter of getting the three government agencies responsible for standards to sign on to the effort. We intend to take the work product of a trilateral agreement and aggressively sell it to each of the Latin American countries, as well as to the supranational trade bodies in Latin America -- Brazil, Argentina, Uruguay and Paraguay -- and the Andean market, led by Colombia and Venezuela.

TMA is also working closely with the Japan Toy Association as Japan begins to discover 20th-century living under a U.S. type of product liability law. At a recent meeting of the boards of the two associations, which included the CEOs of the only billion dollar toy companies, the following declaration was made:

> "[that the associations will]...work together to obtain a single world toy safety standard based upon universally accepted hazard analysis protocols as quickly as possible."

Where Do We Need Help?

Let me set those of you in government at ease. We do not need funds nor are the suggestions that we have costly.

What we are asking for is support in our effort to make the U.S. voluntary and mandatory standards the world standard under ISO. While there has been a long history of support between the private sector and the technical and enforcement staffs of CPSC in manufacturer education as well as in the ASTM process, we now need the leadership of the Commission to support our efforts in international bodies to sell what we know to be the best standard in the world.

On behalf of the entire U.S. toy industry, we sincerely hope that this conference will become a major step forward in our goal of a single world toy safety standard.

HARMONIZATION MEANS STRONG STANDARDS

Mark Silbergeld
Co-Director, Washington Office
Consumers Union

As a result of new trade agreements (North American Free Trade Agreement and the General Agreement on Trade and Tariffs, 1994), there is increased movement by governments to harmonize product safety standards. These agreements, including the Agreement on Technical Barriers to Trade (TBT) [see p. 75], which govern standards for products under jurisdiction of the U.S. Consumer Product Safety Commission, call for harmonization. Members of these agreements have obligations to participate in and make good faith efforts toward harmonization. GATT is the more broad in scope of the two agreements, encompassing most of the world"s commercial powers, and will be the driving force behind harmonization activities.

International product safety standards have an increased role since the establishment of the World Trade Organization, because they may be used as one measure of whether a more stringent national standard is primarily an unjustified barrier to trade.

At the same time they call for harmonization, the TBT and other GATT 1994 agreements also guarantee World Trade Organization member nations the right to choose their own levels of protection from various risks to human life, health and safety, and to take measures needed to achieve those levels of protection. The Uruguay Round Agreements Act [see p. 76], the U.S. legislation that implements those agreements, codifies these principles in U.S. law.

The principles of harmonization and national right to safety may produce potential tensions. Sharp differences in national preferences could put the U.S. at odds with some trading partners in the harmonization process, leading to inability to harmonize some standards or classes of standards, or even to U.S. refusal to accept harmonized international standards less stringent from a safety standpoint than our own.

On the other hand, the enormous role of the U.S. in the international economy and in standards-setting also means that the principles of harmonization and national right to safety can be used together to assure strong, harmonized international standards that do not compromise reasonable, existing U.S. standards. This outcome is one that U.S. consumers expect. It will mean that U.S. products will find acceptance in countries in which consumers hold similar expectations. Standards-setters and producers must not overlook consumer confidence in the safety of

products as an essential factor in marketing. And government decision-makers must

not overlook the relationship between maintaining strong standards and public confidence in these recently-negotiated trade agreements.

AGREEMENT ON TECHNICAL BARRIERS TO TRADE (GATT 1994)

Selected Provisions Related to Product Safety Standard Harmonization

1. The preamble recognizes: "that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human...life or health..., at the levels which it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade...."

2. The preamble also recognizes: "the contribution which international standardization can make to the transfer of technology from developed to developing countries."

3. Article 2.2 provides that legitimate objectives justifying trade-restrictive standards include: "...protection of human health or safety...."

4. Article 2.4 provides that international standards should be used but recognizes exceptions when they "would be an ineffective or inappropriate means for the fulfillment the legitimate objectives pursued...."

5. Article 2.5 provides that when a technical regulation to fulfill a legitimate objective "...is in accordance with relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade."

[N.B.: Regarding the parallel provision in the SPS provisions, the U.S. Trade Representative has stated that the opposite presumption does <u>not</u> apply, i.e., a difference from international standards is <u>not</u> presumed to create an unnecessary standard.]

6. Article 2.6 calls on members to participate in the processes of harmonizing standards "...with a view to harmonizing technical regulations on as wide a basis as possible."

7. Article 2.7 calls on members to consider acceptance as equivalent the technical regulations of other members even if they are different, "...provided they are satisfied that these regulations adequately fulfill the objectives of their own regulations."

URUGUAY ROUND AGREEMENTS ACT OF 1994

Selected Provisions Related to
Product Safety Standard Harmonization

Section 102 (a)(1). "UNITED STATES LAW TO PREVAIL IN CONFLICT.---No provision of any of the Uruguay Round Agreements nor the application of any such provision to any person or circumstance that is inconsistent with any law of the United States shall have effect."

Section 102(a)(2). "CONSTRUCTION.--Nothing in this Act shall be construed...to amend or modify and law of the United States, including any law relating to...the protection of human, animal or plant life or health...or...to limit any authority under any law of the United States...unless specifically provided for in this Act."

WRAP-UP SESSION

BUILDING THE FOUNDATION: HONING THE TOOLS

Moderator: Colin B. Church, Voluntary Standards & International Activities Coordinator, U.S. Consumer Product Safety Commission

Commenters: Linda Horton, Director, International Policy Staff, Food and Drug Administration (FDA)

Mary McKiel, Director, EPS Standards Network, U.S. Environmental Protection Agency (EPA)

Steven Spivak, Chairman, Consumer Policy Committee, International Organization for Standardization (ISO) General Assembly; University of Maryland

Erich Linke, Principal Administrator, Competition and Consumer Policy Division, Organisation for Economic Co-operation and Development (OECD)

Nancy Harvey Steorts, President, Nancy Harvey Steorts International; ex-Chairman of CPSC

Jean Wong, Chief, Policy, Planning and Information, Product Safety Bureau, Health Canada

Edward Becker, Snell Memorial Foundation

For CPSC: Mary Sheila Gall, Vice Chairman and Commissioner
Thomas H. Moore, Commissioner
Bertram Robert Cottine, Executive Director
Ronald L. Medford, Assistant Executive Director for Hazard Identification and Reduction
Harleigh P. Ewell, Office of General Counsel
Eric Stone, Office of Compliance and Enforcement

WRAP-UP SESSION
BUILDING THE FOUNDATION: HONING THE TOOLS

The wrap-up session provided members of the audience a chance to discuss options, opportunities and recommendations on standards-harmonization with CPSC commissioners and senior staff. Below is a summary of their comments in the order they were made. A summary of general observations and specific recommendations from the panel presentations and the wrap-up session follow the comments section.

COMMENTS

Linda Horton, Director, International Policy Staff
Food and Drug Administration

I applaud the Commission for having this meeting and wonder if there is something we can do to continue the momentum that started here today. What I would like to see is some banding together of at least government agencies that have an interest in product safety in order to continue discussions about how standards can help us carry out our public missions and at the same time help U.S. firms continue their competitiveness. Maybe there is some way to have a government-led core group that periodically reaches to industry and consumer groups for input. We probably could benefit from more dialog of this sort as we move toward more harmonized international policies.

Mary McKiel, Director, EPS Standards Network
U.S. Environmental Protection Agency

My congratulations for an absolutely superb day.

In this global era where trade, environment, health and safety are all emerging, it would be a good idea to have some informal mechanism whereby federal agencies are able to discuss with one another the issues that each of us faces, then what we collectively need to do to get the U.S. in the best possible position.

Steven Spivak, Chairman, Consumer Policy Committee (COPOLCO),
International Organization for Standardization (ISO) General Assembly;
University of Maryland

COPOLCO offers an excellent opportunity for getting involved in international consumer product issues. ANSI is the sole U.S. representative to the ISO. United States participation in ISO/COPOLCO is overseen by ANSI"s Consumer Interest Council. I encourage you to join this group if you are interested in these issues.

COPOLCO is involved in generic international safety standards, such as those dealing with child safety, product safety and the use of consumer products. These are different from specific technical product standards that are developed by ISO technical committees. Do any of you think it would be useful for the ISO to have a generic ISO consumer products technical committee or an ISO consumer services technical committee? For example, (in the U.S.) the ASTM F-15 Committee on Consumer Products is writing standards not otherwise covered by technical committees. Is there an analogy to promote international safety standards in a generic type of committee in the ISO or elsewhere that you would like to see?

Service standards can have a major impact on product standards. For example, should there be a national or international standard on complaints-handling and -resolution if consumers have a problem with consumer product safety? This is another area I hope you find important.

Erich Linke, Principal Administrator, Competition and Consumer Policy Division, Organisation for Economic Co-operation and Development (OECD)

The OECD has 25 member countries that represent the major trading areas of the world. Thus, we feel we can make a reasonable contribution in issues that arise at the interface of consumer policy and international trade.

Since 1969, the OECD has had a committee on consumer policy. We have benefited very much from the active contribution from the United States, particularly from the U.S. Consumer Product Safety Commission. A number of concepts that are now recognized throughout the OECD and that concern the whole idea of product safety laws in general were inculcated through the Consumer Product Safety Commission. What we had before in Europe were mainly vertical, product-by-product regulations. This contribution has made the OECD more homogeneous

We have worked on international trade issues since the mid-1980s. We have done some pioneering work as a secretariat. One of our reports dealt with standardization and the consumer. The conclusion we drew is that there are three major trends: 1) regionalization of the standardization process; 2) a tendency toward the use of voluntary versus mandatory standards; and 3) the increasing need for more mutual recognition of standards as opposed to detailed harmonization of specifications. That is why we have introduced the idea of mutual recognition.

As a final point, I wish to announce an international conference in December 1995 on product safety standards, conformity assessment and their impact on international trade. The purpose is to see the reality of trade barriers that arise in the area of safety regulations. We request the support of CPSC and the business community in the areas in which we are working.

Nancy Harvey Steorts, President, Nancy Harvey Steorts International; ex-Chairman, CPSC

Special thanks for bringing us to this outstanding conference. CPSC is now reaching a new height. This conference will bring the importance of this Commission to the international arena. I challenge you to move forward and be aggressive in your action. I was very impressed with what the gas industry has done and also what the toy industry is now asking the Commission to do. As a catalyst, CPSC can bring this international toy standard to fruition. I would like to see you start with attempting to harmonize standards within NAFTA. I hope this conference will be just a beginning to the great new heights to which the Commission will rise.

Jean Wong, Chief, Policy, Planning and Information, Product Safety Bureau (PSB), Health Canada

I believe the memorandum of understanding (MOU) between the PSB Canada and CPSC enhances the working relationship of the two organizations and promotes a greater understanding between the people who work in the two organizations. This MOU has been in effect since June 1993, pursuant to the Free Trade Agreement between Canada and the U.S. So far, it has been a very productive arrangement between two good neighbors. Benefits accrue from regular communications and effective working ties on a government-to-government basis. This bodes well for consideration within a global context. The Commission might wish to consider similar relationships with its counterparts in other governments.

Edward Becker, Snell Memorial Foundation

I wish to reemphasize not just the need for standards, but standards and conformity assessment. Our findings with crash helmets show that standards by themselves are insufficient to guarantee the safety of products in the market and especially to guarantee the effectiveness of imported products. Mandatory U.S. standards, and probably all voluntary programs, should include a specific means of conformity assessment; that is, certification and after-market monitoring.

OBSERVATIONS AND RECOMMENDATIONS
(From Panel Presentations and Wrap-up Discussions)

1. Increased product standard harmonization would enable the Commission to create alternatives to costly product recalls, reduce regulatory costs of labeling and others means of informing the public about product hazards, more effectively promote educational activities, minimize protracted legal disputes and deal more effectively with the imported harmful products.

2. Effective trade policies designed to expand exports and create jobs must be accomplished by harmonizing up, not down. As a matter of United States policy, safety must not be compromised.

3. The U.S. Government and American industry can, and should, work together to develop a mutually acceptable position tying the benefits of product standard harmonization to economic growth and consumer protection.

4. CPSC first should attempt harmonization on a pilot project basis by developing a compatible standard with Canada, e.g., a toy standard, then attempt to gain acceptance of an effective international toy standard.

5. Federal regulatory agencies, with an interest in product standard harmonization, should cooperate in sharing information, expertise and strategies to contribute to a stronger and more unified comprehensive U.S. harmonization effort.

6. The memorandum of understanding between CPSC and its counterpart, Health Canada, should serve as a model for future bilateral agreements between CPSC and its counterparts in other countries.

7. The establishment of a technical committee on consumer product safety should be considered under the International Organization for Standardization to develop harmonized international standards.

8. CPSC should continue to actively participate in interagency groups developing and implementing U.S. trade agreements. CPSC should become more active in international organizations such as the Organisation for Economic Co-operation and Development to develop responsible policies affecting consumer safety, product standards and international trade harmonization.

9. Where necessary, CPSC should support bilateral negotiations with Europe and other countries to generate mutual recognition agreements covering testing and inspections.

10. CPSC should consider a policy of accepting the integrity of accreditation systems and the results of independent laboratories that support the U.S. market as a means of recognizing the safety of products from abroad.

11. In dealing with foreign regulators, CPSC should adopt positions that promote the lowest cost product certification requirements commensurate with product risk.

12. CPSC should consider the potential for international harmonization of product standards and other regulatory requirements with countries that involve heavy U.S. exports and imports.

CLOSING REMARKS

CLOSING REMARKS

Ann Brown
Chairman
U.S. Consumer Product Safety Commission

I wish to thank you all for coming. Today we have established the need for international harmonization of standards, and I hope that CPSC will serve as a catalyst for action. One idea that the Commission might implement is to conduct a pilot project to develop an international standard based on a CPSC or ASTM standard and working, perhaps, with Canada. We'll be looking at this as well as other ideas that were mentioned today.

Finally, the standards-harmonization process must harmonize up -- there must be no compromise in product safety.