EXECUTIVE OFFICE OF THE PRESIDENT OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE WASHINGTON, D.C. 20508

November 14, 2008

Gwen Hinze Electronic Frontier Foundation 454 Shotwell Street San Francisco, CA 94110

Dear Ms. Hinze:

This is an initial response to your e Freedom of Information Act, requesting of June 11, 2008 as amended by your fax of July 24, 2008 requesting the release of certain records concerning the Anti-Counterfeiting Trade Agreement ("ACTA"). We have completed preliminary processing of the records you have requested in paragraphs 1 through 5 of your July 24, 2008 modification of your request.

Please be advised that we are releasing fifty-four (54) documents in response to your FOIA request.

We are still awaiting a response from some third parties in order to determine whether any additional documents can be released to you. We expect to have a definitive answer early next week. At that time our FOIA office will provide you with a final response in regard to the records requested in subparagraphs 1 through 5 of your request and inform you of the number of records we are not disclosing and the reason for withholding them.

Should you have any questions regarding this communication, please contact Vanessa Brinkman at (202) 616 - 5462.

Sincerely,

David Apol
Chief Counsel for

Administrative Law

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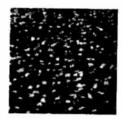
Administrative Law







ECPA's position the Anti-Counterfeiting Trade Agreement





Brussels 14th July 2008 PP/08/RR/17724

The European Crop Protection Association, ECPA, representing the major R&D companies in the manufacture, distribution and supply of plant protection products (PPP), welcomes the Commission's initiative of working with other governments on an Anti-Counterfeiting Trade Agreement, ACTA.

Intellectual property is one of the EU's key competitive assets and is fundamental in the continuous development of pesticides that minimise risks to human health and the environment, thus contributing to the success of sustainable agriculture now and in the future.

There is growing concern internationally about the increasing misappropriation of intellectual property rights, IPR, of all industries around the world and this applies to the global **pesticide** market.

In Europe alone ECPA is seeing a growth in counterfeit and illegal PPPs in **many EU** countries. Most products emanate from China but their distribution routes into Europe can be complex.

Pesticides and plant protection products are regulated through legislative measures in almost all countries around the world. Of particular concern is the ongoing protection of human health and the environment by governments, not least the EU, and the continued desire to strive to have the highest levels of protection in this sector.

The consequences of counterfeit and illegal PPPs cannot be understated; they pose significant health risks to farmers and consumers together with an adverse impact to the environment. All counterfeit PPPs are unregulated and untested and can contain dangerous manufacturing impurities and by-products together with banned solvents and other harmful ingredients. Counterfeiters have no concerns about farmer and consumer protection and will readily use banned and hazardous materials in counterfeit and illegal PPPs in order to realise huge profits.

Definition of Counterfeit Products

ECPA believes that the provisions of the ACTA, namely; International Cooperation, Enforcement Practises and Legal Framework provide a framework under which issues can be discussed. There are certain areas that need to be addressed within the structure of ACTA one of which is the definition of counterfeit products.

Being a regulated industry, most countries impose stringent checks on PPP's before they enter the marketplace to ensure they minimise the risks to human health and the environment.

Examples of commonly found counterfeit products, include sophisticated copies of the product and packaging of branded and trade-marked products usually still within patent protection. Others are poor copies of known products, whereby the packaging and labelling are of poor standards and the contents could be anything from diluted legitimate products or obsolete stocks to crude solvents and other unknown materials. All these products are illegal and therefore compromise the high standards of human health and environmental protection that the regulations are designed to protect, but by definition may not contravene IPR. Likewise as PPPs are regulated before entering the market, appropriate rights are assigned to the use of data generated to secure the registration by the principle registrant. Data Protection for PPPs is a right within WTO, TRIPS and should always be considered in the same context when counterfeit and illegal PPPs are considered.

ECPA encourages the ACTA to broaden its overall definition of counterfeiting to ensure that protection of regulatory data is adequately recognised together with illegal products (not necessarily violating IPR), but illegal within the context of their own regulations.

International Cooperation

ECPA believes that international cooperation between enforcement agencies is of the highest priority in any ACTA. The sharing of information and the development of global databases through which intelligence can be channelled would provide links between people and organisations operating illegally around the world.

ECPA believes that the World Customs Organisation, WCO, should take a leadership role and establish a global customs intelligence process that can be used to identify, track and monitor potential counterfeit and illegal activities across the world. WCO should also foster the exchange of experiences between customs and enforcement agencies (such as border guards, road traffic inspection, plant protection inspection and police) from different countries on a regular, maybe annual basis.

This would help countries in developing technical capacity and allow the exchange of information between agencies that will benefit those with less sophisticated internal systems. In addition, existing pan national entities, like the European Commission or similar on other continents should take a leadership role in information and best practice exchange. ECPA would also like the ACTA to consider other international bodies such as Food and Agricultural Organisation (FAO) and World Health Organisation (WHO) to become involved in any global initiative.

Enforcement Practises

ECPA strongly supports the establishment of enforcement practises that promote strong intellectual property protection in coordination with the rights holders and trading partners. Key areas that should be considered include;

- Raising the priority of anti-counterfeit measures at a global level
- Within regulated industry sectors it is paramount that regulation is supported by enforcement. Reliance on regulation to protect the consumer and the environment cannot be sustained without appropriate structured enforcement activities that continue to monitor the market place for violations of product integrity and IPR. (With PPPs governments are required to regularly monitor and report on residues in edible crops to help ensure good agricultural practise is applied and that maximum residues levels are not exceeded. Similar regular monitoring of products for specification compliance would help deter illegal and counterfeit products.)
- Raising the awareness of the consumer about the importance of IPR protection and the need to ensure that regulated industries are not undermined.
- Establishing specialised intellectual property expertise in enforcement agencies so
 that cases can be dealt with efficiently and effectively and that IPR protection is seen
 to be of priority.
- Developing sector groups between the public agencies and industry to ensure the best understanding of key industry sectors and the issues in any sector specific to its business and products that may call for additional and different approaches when dealing with counterfeit products.
 - Within the pesticide sector it is important that enforcement agencies have specialised knowledge to handle counterfeit and illegal PPPs.
 - Since they are untested, unregulated and their contents unknown, all counterfeit and illegal PPPs should be dealt with as toxic waste and as such need to be contained, transported and destroyed using agreed international procedures developed by industry and governments.

Legal Framework

ECPA fully supports the need for strong and modern legal frameworks so that law enforcement agencies, the judiciary and private citizens have the most up to date tools to bring counterfeiters and illegal traders to justice. Such areas would include:

Border measures

The movement of active substances bulk formulated product and final formulated and packed product (ready for sale) are the most common ways of transporting pesticides around the world. Recognition of such and the establishment of common border measures with these three commodities would facilitate better detection of illegal shipments.

Civil enforcement.

o The ability to bring rapid civil enforcement action is strongly supported, due to the very short selling season for PPP's.

Criminal enforcement

 ECPA strongly encourages that all activities involved in counterfeit and illegal trade are dealt with through criminal enforcement measures thus providing a robust process of dealing with those who counterfeit products and deal in illegal trade.

Internet

 The use of the internet is increasing across all business sectors and it provides additional opportunities to exploit counterfeit and illegal sales of PPPs.

Free Trade Zones

 It will be important that the concerns about the development and use of free trade zones are addressed in any ACTA. Whilst such zones enable efficient transhipment of goods there is growing concern over their use as umbrellas for counterfeit activities.

Free Trade Areas

• Within any geographical area whereby countries come together to facilitate free trade it is important to address the enforcement criteria used to free trade/parallel trade products. Free trade areas especially in the pesticide sector are being used as mechanisms to legitimise illegal trade through substitution practises.

ECPA is encouraged that anti-counterfeiting measures are being addressed at a global level and welcomes the initiative of the ACTA. Like any agreement it will be necessary to give it some legal basis under which to operate, such that those who sign up to the agreement can be brought to account if their standards fall below those agreed.

ECPA also encourages the EU to promote the adoption of individual measures, once agreed by the partners, so that we do not have to wait until all measures are agreed to allow the ACTA to become effective.