

Risk Management of Highly Hazardous Pesticides – CropLife International's Approach

Industry approach

Acknowledgement

- CropLife International know keeping HHPs available is a sensitive issue. Before explaining what we are doing, we want to emphasise one point: we welcome a constructive and informed debate on the action that should be taken about HHPs. No stakeholder concerned with this issue can claim to have all the solutions or be right 100% of the time – and this includes CropLife International.
- CropLife International believe improvements will come through the continued sharing of ideas, knowledge, and information. We already take action on pesticide safety in partnership with governments, NGOs and other stakeholders, and we hope this collaboration will continue.

Industry approach

CropLife International activities include

- Portfolio Review (Continuous activity that followed on a CLI-co-ordinated voluntary review by all member companies of their entire portfolios against the 8 HHP criteria)
- Support to the FAO registration toolkit (technical input & promotion)
- Promotion of the Code (e-learning tool)
- GHS implementation (CLI joined the High ambition coalition for the post 2020 chemical framework)
- Responsible Use programs (e.g. improved application, PPE)
- Regulatory Capacity Building (support for simplified risk assessment)
- Establishing Spray Service Providers Programs
- Industry guide on adherence to the Code/HPPs
- Risk Mitigation workshops (with all HHP stakeholders)
- Promotion of IPM (e-learning tools, projects in partnership)
- Engagement with UN sectors on HHP policy (FAO/WHO JMPM, SAICM/UNE)

Industry approach

Code of Conduct sets the basis for HHP activities

Relevant Terms & definitions by the 2013 revised CoC

- “...pesticides that are acknowledged to present particularly **high levels of acute or chronic hazards** to health or environment according to internationally accepted classification systems such as WHO or GHS or their listing in relevant binding international agreements or conventions. In addition, pesticides that appear to cause severe or irreversible harm to health or the environment under conditions of use in a country may be considered to be and treated as highly hazardous.”
- Of relevance to public health, the Code now **focuses on risk reduction** by calling on countries to identify and, if necessary, remove from use, **highly hazardous pesticides**;

Code of conduct (cont.)

- (*§ 7.5*) **Prohibition** of the importation, distribution, sale and purchase of highly hazardous pesticides **may be considered if, based on risk assessment, risk mitigation measures or good marketing practices are insufficient to ensure that the product can be handled without unacceptable risk to humans and the environment.**
- (9.4.1) support the process of information exchange and facilitate access to information...
(incl.) pesticide hazards and risks
& **alternatives to highly hazardous pesticides**

Other considerations:

(*§ 3.6.*) Pesticides whose handling and application require the use of personal protective equipment that is uncomfortable, expensive or not readily available should be avoided, especially in the case of small-scale users and farm workers in hot climates(6).

HHP Portfolio Review

Voluntary Joint Portfolio Review by all CropLife Funders

Process

- Identification of active substances meeting criteria for HHPs (where relevant: formulants)
- Risk assessment of formulations based on a.i.'s and/or formulants triggering HHP criteria
- As needed, risk mitigation of formulated products

Note:

- *Criteria based on FAO/WHO HHP guidelines (2016)*
- *Portfolio reviews are not one off, but continuous by each member company*

Portfolio Review

Outline of common approach taken by members

- Underlying principle of risk assessment
 - i.e. Tiered approach (simplified conservative assumptions to real field scenarios), use of data from *local use assessments*, necessarily apply setting of models, scenarios & inputs used in regional decision making
- Information on *local* uses
 - Based on surveys of agricultural practises (crop/equipment/application know how)
 - Company network (such as technical services, sales force, etc.)
- Assessment of exposure
 - i.e. use of suitable data following clear hierarchy (company own measurements in field > published data > estimations from similar situations > estimates based on extrapolation)
- Assessment of effects
 - International accepted reference values (such as AOEL)
- Mitigation measures
 - Label change, stewardship, crop label withdrawal, formulation change

Results

OUT OF
6,400

crop protection products evaluated
in 2015 and 2016...

85% were not HHPs

10% were HHPs that can be used
safely and responsibly

2.5% required risk mitigation measures
or were withdrawn from the market

2.5% are under further evaluation

Portfolio Review

Results (2)

Mitigation measures (for 160 of products w/assessment completed)

- 125 country mitigations including *use* or *scenario changes* and *geographic* withdrawals
- 97 products withdrawals in LIC markets
- 14 formulants phased out and 2 active ingredient phase-outs (some other decisions underway)
- (2 a.i. phase-outs started already before review)

Key learnings - addressed by ongoing CropLife International Commitments



1. Identified common issues for accelerated stewardship activities
 - Availability of protective clothing (PPE)
 - Risks of exposure involved with Knapsack sprayers
 - Understandability of Label information
 - Pesticide storage and container management
2. Recognized regional hotspots
 - South East Asia, West Africa and Andean Region
3. Need to engage generic & local crop protection industry
 - Limited market reach in some LICs
 - Illegal trade & counterfeit pesticides
4. Bringing innovation in LIC markets
 - Challenge w/ handling intellectual property & confidential business information
5. Adjusted approach to capacity building
 - Encourage stakeholder/policy maker dialogue by focusing on risk mitigation

Alternatives

Broadening the farmers crop protection toolbox

- Improved screening processes for new actives
 - Improved acute & chronic toxicity profiles, favorable env. behavior etc.
- Significant investments in Biologicals
- Increased focus on integrated crop solutions
- Projects dedicated to smallholder farmers
 - E.g. Spray Service Providers in West Africa
- Continued promotion of IPM
 - CropLife industry agrees with FAO for careful consideration of “all available pest control techniques”
 - Promote interventions to levels that are economically justified and reduce or minimize risks to human health and the environment.
 - Global training programs in IPM & responsible use with partners
 - GIZ projects in Vietnam and Thailand and information promoted through BRIA and SRP partnerships.

Ending Use («Banning»)

Any of those decisions need careful consideration

Impact on farmers toolbox (very often already limited in developing countries, i.e. small numbers of active ingredients)

- Need for risk – benefit considerations, i.e. impact on farmer productivity (yield, cost)
- Resistance risk for alternative products by overuse
- Limited control options with severe pest or disease outbreaks (emergencies)

Governance of product phase-out's is often limited

- Illegal trade across neighboring country borders
- Counterfeits

Replacement of products requires a regulatory framework that encourages innovation

- Protection of Confidential business information and Intellectual Property

New technologies might allow for different and effective risk mitigation

- Products of current concern might become viable options again (precision farming, use of drone technologies etc.)

CropLife Risk Assessment Capacity Building



Available Modules & Tools for partnership workshops in LIC's

Interactive sessions

- ✓ Regulatory Frameworks/ Principles of Good Regulation
- ✓ Introduction to Risk Assessment
- ✓ Environmental Risk Assessment
- ✓ Operator Exposure
- ✓ Human Risk Assessment

Specific Trainings

- ✓ Global Harmonized System (Labelling)
- ✓ Formulation types
- ✓ Specifications & Equivalence

Risk assessment (RA) tools

- ✓ Operator RA
- ✓ Ecotoxicology – Tier 1 RA
- ✓ Drinking water RA
- ✓ Dietary Exposure RA
- ✓ (demonstration & hands-on training)

General topics

- ✓ Protection of Regulatory Data/ Confidential Business Information
- ✓ Implementation & enforcement
- ✓ Risk perception, communication & management

Capacity building activities

- Multiple internal and government related Workshops/Trainings for awareness creation in HHP management, Risk Assessment, GHS implementation in Africa and Middle East countries, Latin America and Asia
- Support to the FAO toolkit development (e.g. Residue Dossier, Exposure assessment, RA for Drinking & Surface water etc., soil)
- Workshops with IUPAC - Joint risk assessment capacity building activities (Asia, Latin America etc.)

Full activity reports provided to SAICM (EPI's and OOG) in 2016 and 2018

HHPs

Focus on awareness raising

- Continued implementation of HHP portfolio review findings by CropLife International members
- Support for SAICM and HHP policy issues
- Outreach to generic industry
 - Associations, i.e. Agrocare
 - Direct contact w/larger companies
 - Via CropLife countries association network (e.g. Kenya, Thailand)
- Awareness raising of HHP guidelines w/regulators
 - Asean Harmonisation of TG for Pesticide Registration Management; African regional Hub meetings

HHP Risk Mitigation

Mainstreaming activities w/governments, IGO's & industry

Successful pilot in West African Region

- Key policy decision makers from environment and agriculture ministries participated, incl. SAICM focal points
- Regional representation from FAO
- Appreciated shift to practical mitigation aligned with SAICM regional commitments
- Agreement to develop further multi partner programs at country level
- CropLife approach and assumptions validated
 - Shift to dialogue and enabling stakeholder engagement
 - Risk mitigation creates the momentum for dedicated capacity building activities

Risk Mitigation workshops

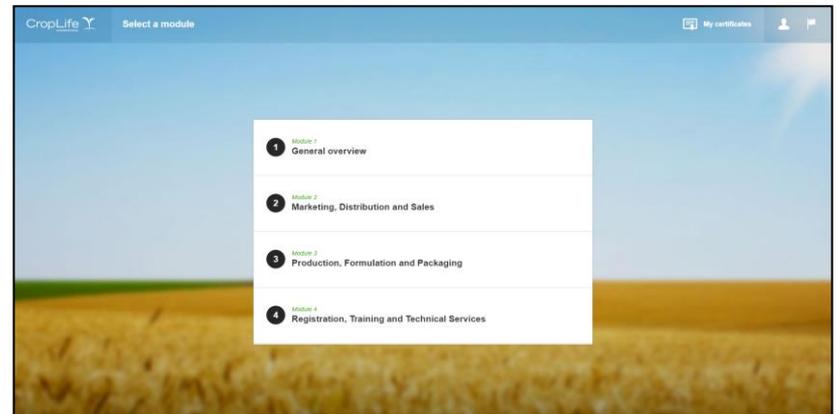
Expanded to Thailand, Kenya, Latin America

- Platform for policy decision makers from environment and agriculture ministries, incl. SAICM focal points to identify & discuss pesticide management issues in country, incl. HHPs
- Regional representation from FAO, UNEP
- Involvement of local generic industry
- Shift to practical mitigation aligned with SAICM regional commitments
- Development of multi partner programs at country level – based on identified priorities
- CropLife introduction of risk mitigation tool box
 - Shift to dialogue and enabling stakeholder engagement
 - Risk mitigation creates the momentum for dedicated capacity building activities

Code of Conduct e-Learning Tool

Code of conduct e-learning tool

- Developed by CLI to improve knowledge of the Code
- Systematic roll out by CropLife International members
- Mandatory for regional/country association memberships
- 10,000 participants
- Available in 14 languages: EN, ES, PT, RU, FR, DE, PL, TH, VI, CN, JP, ID, AR, IN



Mode of Action Labelling Initiative

MoA Labelling Initiative

Resistance Management (RM)

- Resistance is a critical focus for industry and part of our overall sustainability commitment
 - Pest resistance is more likely to occur after regular use of same mode of action (MoA) pesticides.
 - MoA information empowers farmers in implementing RM
- CropLife International and its resistance action committees (RACs) address this by advancing understanding of MoA
- RACs provide communication resources on MoA
 - E.g. online, training modules, posters, brochures etc.

MoA Labelling Initiative

Industry Commitment



**CLI members have made a voluntary
commitment to include MoA information on all
product labels by 2023**

MoA Labelling Initiative

Industry Commitment

- Including MoA information on product labels is critical for growers to manage resistance
 - However, MoA labelling is only required in a small number of countries
- CLI encourages **all** pesticide manufacturers to include MoA information on their labels
- CLI also encourages regulatory authorities to consider the mandatory use of MoA labelling

Partnership projects on IPM and Responsible Use with GIZ in Vietnam

Implementation

Overview

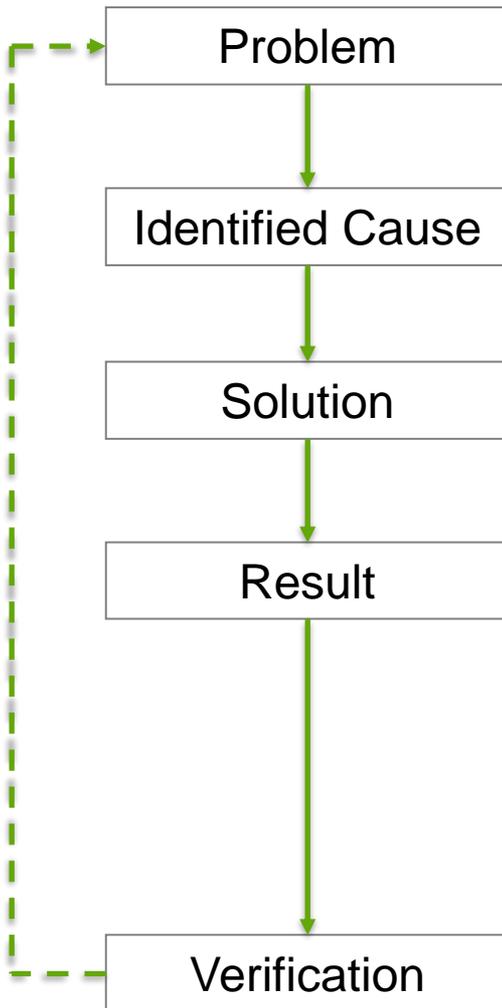
- Partnership with GIZ and the Plant Protection Department
- Target to train 15,000 farmers and 300 retailers in IPM
- Located in three districts in the Mekong Delta
- Implementation through the Southern Region Plant Protection Centre
- Training follows Adoni Model (one directly trained farmer trains four other farmers)
- 2015-17, further promoted in Thailand 2018-21

Rice IPM

Outcomes

- 15,000 Farmers and 400+ retailers trained
- 67 Farmer clubs created
- Understanding of natural enemies (3): 47 – 89%
- Understanding of MoA: 66 – 80%
- Understand Label: up to 99%
- PPE: 52 – 99%
- Number of sprays reduced by 30%
- Net income increase: 14 – 17%

Summary



Poor pest control: resistance, resurgence
User and Environmental Contamination

Poor understanding of pest and pesticide
management, Poor advice from retailer
Poor pesticide application

Training in IPM (user and retailer)

Change in Behaviour

- Adoption of IPM
- Proper Handling and Application of pesticides
- Reduction in unnecessary pesticide use

User Surveys

Reduction in pest outbreaks

Increase in farmer income

Fall Armyworm (FAW)

CropLife Partnership with USAID

Ethiopia – use of the SSP model

- **FAW IPM Training:** United States Agency for International Development (USAID) partnered with CropLife Africa Middle East
- Select and train a network of Spray Service Providers (SSPs) to help farmers tackle FAW
- By January 2019 the project trained 240 SSPs who will service 7,680 farmers across 4 regions of Ethiopia
- Network of FAW IPM trainers of trainers established in W, Sth and Eastern Africa

Spray Service Providers

Village based crop protection service providers

- SSPs are trained in collaboration with donor funded and NGO projects.
- SSPs trained in IPM, Responsible Use, Resistance management, procurement procedures, container management.
- Partnerships include IDE, DFID, USAID, SNV, GIZ.
- Since 2009, over 11,000 SSPs have been directly trained.
- Every year they provide services to 130,000 farmers.
- Partners e.g. IDE have taken forward the model

The pre-read material provided with this overview has more on:

- IPM & responsible use training**
- Obsolete stocks removal**
- Container Management**

here: SAICM brochure

<https://croplife.org/wp-content/uploads/2019/03/SAICM-v3.pdf>

Examples of HHP management by CropLife International Members

Member specific approaches to HHP management

- Examples by Bayer, BASF & FMC* highlighting 3 directions how members approach the issue:
 - 1. Stewardship (BASF), 2. Risk Mitigation (Bayer), 3. Regulatory (FMC)
- CropLife Members are all aligned on the same principles in their approaches:
 - Science-based and evidence-led
 - Providing a transparent dialogue with stakeholders
 - Leading Industry improvements by example

Example 1

BASF stewardship activities

Suraksha Hamesha Trainings in India Responsible and Safe use for HHPs and Beyond

How does it work?

- Dedicated direct farmer training on the nine steps of responsible use of crop protection products and personal protection measures
- Along with the training, BASF offers the Sanrakshan Kit, an affordable set of personal protective equipment
- In collaboration with local governments



~3.000
Agriculture dept.
Officials participated



>1.800
Channel partners
reached



>21.000
Students reached



>29.000
Spray men trained



~200
Schools covered



~150.000
Farmers trained



Plus
>2.500.000
Digital outreach

BASF supports use of HHPs only with appropriate Product Stewardship measures



Example 1 cont.

BASF stewardship activities

Suraksha Hamesha Trainings in India 9 Steps of Responsible Use of Crop Protection Products

<p>1</p> <p>PURCHASE </p>  <p>Seek Advice before buying pesticides. buy them from authorized retailers and ask for a bill.</p>	<p>2</p> <p>TRANSPORTATION </p>  <p>Never transport pesticides together with food items- fruits and vegetables.</p>	<p>3</p> <p>STORAGE </p>  <p>Always store pesticides in a locked and well ventilated place which is beyond the reach of children and animals.</p>	<p>4</p> <p>READ PRODUCT LABELS AND LEAFLETS </p>  <p>Always read product labels and leaflets carefully.</p>	<p>5</p> <p>MIXING </p>  <p>Do not mix with bare hand, use stick for mixing. In case nozzle is blocked do not blow with mouth wear the right personal protection equipment while mixing & spraying.</p>	<p>6</p> <p>TRIPLE - RINSE PESTICIDE CONTAINERS </p> <p>Follow These Steps (3) Times</p>  <p>1. Quarter fill the container with water. 2. Close the container and shake it for 30 seconds. 3. Empty all solution from the container in the tank. Hold it there for 30 seconds or more. Protect your health. Puncture the container so it cannot be reused.</p>
<p>7</p> <p>DO'S AND DON'T'S WHILE SPRAYING PESTICIDES </p>  <p>Never eat, drink or smoke while you are spraying pesticides. Preferably spray pesticides early morning or evening and do not spray when it is windy.</p>	<p>8</p> <p>DISPOSAL </p>  <p>Do not throw empty pesticide containers in water bodies or in the field or near livestock and never use empty pesticides containers for storing food or water.</p>	<p>9</p> <p>CARE AFTER SPRAYING PESTICIDES </p>  <p>After spraying pesticides, wash Personal Protection Equipment, wash your clothes and take a bath.</p>	<p>...thereby helping farmers to stay safe and to protect the environment</p>		

Example 2

Bayer's commitment to safe pesticide solutions



Bayer's commitment to product safety goes beyond just meeting the local regulatory requirements with our products. In the exceptional cases where our products meet FAO's HHP criteria, we conduct assessments to identify any potential risks based on the locally registered uses. If any potential risks are identified, we implement mitigation measures such as developing new formulations, reviewing the labels and increasing training. If we believe it is necessary, we voluntarily withdraw products from the market.

- 1. Local Risk assessments worldwide:** Bayer has developed specific models to assess the **safety of operators** when they are using our products. We take into account the newest scientific knowledge, the safety standards of reference regulators, of the FAO/WHO and OECD. We pay special attention to uses where farmers may be most exposed.
- 2. Our commitment to transparency:** since 2017, we enable access to Bayer's safety studies. Following this same path, we will make these assessment models transparent.

Example 2 cont.

Bayer's commitment to safe pesticide solutions



3. As **examples of risk management and mitigation**, in 2019 Bayer trained more than **one million farmers** around the world for the safe use and handling of crop protection products.
4. As **additional examples**, in 2012, we stopped selling any WHO acute class 1 pesticides, one of the HHP FAO criteria. We have decided to phase out all carbendazim-based products.
5. Since 2016, we have committed to **only sell products** with active ingredients which have a registration for use in at least one OECD country, or for new active ingredients with a **complete OECD safety data package**.

Example 3

Status of FMC's HHPs



- FMC is continuing to phase out Highly Hazardous Pesticides (HHPs) from our product portfolio.
- We evaluate HHPs using the criteria and process defined by the United Nations Food and Agriculture Organization (FAO) which is the globally accepted regulatory classification scheme.
- At the end of 2019 we ceased our sales of carbofuran in the few remaining countries where it was sold.
- We currently have five HHPs remaining in our portfolio and are identifying those to be phased out over the next two years.
- In 2020, these five HHPs account for less than 0.5 percent of projected global sales.
- Risk assessments and product stewardship programs for the remaining HHPs in the specific countries of sales continues so we are aware of any issues that may occur and can mitigate them immediately.
- Utilization of our Product Stewardship and Sustainability Assessment tool (consists of 35 questions) ensures that we screen out potential HHPs early in the development process of new products.

FMC has a public and steadfast commitment to not develop or sell any new HHPs (judged on science-based application of criteria)