



### CASE STUDY (CSI02):

**A Competent National Authority (CNA) provides information about a decision to the BCH.**

#### Objective:

- To understand what information should be submitted to the BCH after a country 'makes a decision' on importing a Living Modified Organism (LMO) and how it is done through the Biosafety Clearing House (BCH).

#### Scenario

The Competent National Authority of the Republic of South Africa approves the importation of modified cotton DAS-24236-5 × DAS-21Ø23-5 (trade name Widestrike) for intentional release into the environment. What information must the South African competent authority provide to the BCH about its decision? As a resource, please refer to the attached document 'Decision on Insect Protected Cotton Event, DAS-24236-5 × DAS-21Ø23-5 (Trade Name Widestrike™).'

Provide the answer indicating how information can be submitted to the Biosafety Clearing House and which article(s) of the Cartagena Protocol is/are pertinent to this activity. Identify what information is missing in the attached decision.

#### **DECISION ON INSECT PROTECTED COTTON EVENT, DAS-24236-5 × DAS-21Ø23-5 (TRADE NAME WIDESTRIKE™)**

Host Organism / Variety	<i>Gossypium hirsutum</i> L. (Cotton) WideStrike™
Trait	Resistance to lepidopteran pests.
Trait Introduction Method	Traditional plant breeding and selection
Proposed Use	Production of cotton for fibre, cottonseed and cottonseed meal for livestock feed, and cottonseed oil for human consumption.
Company Information	DOW AgroSciences LLC

#### **General Description**

WideStrike™ cotton (OECD identifier: DAS-24236-5 × DAS-21Ø23-5) was produced by cross-breeding two insect-resistant cotton lines: 281-24-236 (OECD identifier: DAS-24236-5) and





3006-210-23 (OECD identifier: DAS-21Ø23-5). Each of these lines expresses an insecticidal protein. This stacked cotton line is a product of traditional plant breeding.

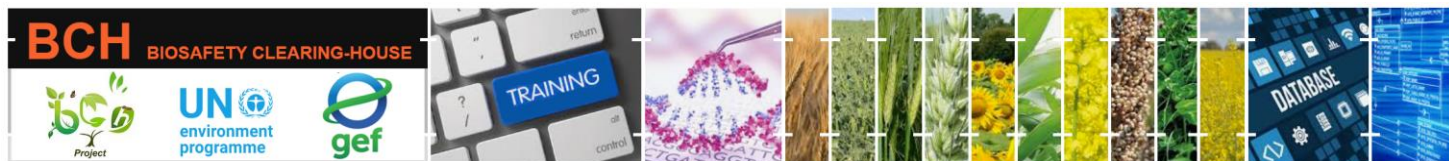
WideStrike™ expresses two novel proteins: Cry1F and Cry1Ac, delta-endotoxins that confer resistance to lepidopteran pests of cotton, such as the cotton bollworm, pink bollworm, and tobacco budworm. The insecticidal protein Cry1F is produced by the *cry1F* gene from cotton line 281-24-236, and Cry1Ac is produced by the *cry1Ac* gene from cotton line 3006-210-23. The *pat* gene is also expressed in WideStrike™. This gene produces the PAT protein (phosphinothricin acetyltransferase), which confers resistance to the herbicide glufosinate ammonium and is inserted solely as a selectable marker during the transformation that led to the production of 281-24-23 and 3006-210-23.

The inserted genes and their gene products in WideStrike™ cotton have a history of safe use and have undergone prior review and approval by several regulatory agencies. No interactions among the gene products or negative synergistic effects are expected in the stacked line. Since neither Cry1F nor Cry1Ac, have enzymatic activity, these proteins do not affect plant metabolism. The PAT protein has a high affinity for L-phosphinothricin, the active ingredient in the glufosinate ammonium herbicide. Cry1F, Cry1Ac, and PAT are, therefore, not expected to interact within nor affect the metabolism of the stacked hybrid.

The South African competent authority has conducted an environmental hazard assessment of WideStrike™ cotton. Data on the effects of the Cry1F and Cry1Ac were assessed separately and in combination to detect possible synergistic effects. No synergistic effects were observed, nor any increase in the host range of non-target organisms, from the stacking of both Cry proteins. No harmful effects to aquatic and terrestrial wildlife were observed, and it was concluded that the cultivation of the stacked line would not be hazardous to non-target terrestrial, aquatic, and soil organisms. Additionally, this approval permits WideStrike™ only to be used in small-scale, experimental field trials grown under conditions of reproductive isolation coupled with additional restrictions and mandatory monitoring of the trial site during the trial and for one year after termination of the trial.

### Mechanics:

Participants should be divided into four groups of four members each. Each group will be assigned a given country. Participants in each group will take turns assuming the BCH National Focal Point role while the rest are National Authorized Users.



Groups and log-in details are summarized below:

Group	Country	Role	User name	Password
1	Greece	NFP	greece.nfp@gmail.com	Abdef1234\$
		NAU	greece.nau1@gmail.com	Abdef1234\$
		NAU	greece.nau1@gmail.com	Abdef1234\$
		NAU	greece.nau1@gmail.com	Abdef1234\$
2	Angola	NFP	angola.nfp@gmail.com	Abdef1234\$
		NAU	angola.nau1@gmail.com	Abdef1234\$
		NAU	angola.nau2@gmail.com	Abdef1234\$
		NAU	angola.nau3@gmail.com	Abdef1234\$
3	Andorra	NFP	andorra.nfp@hotmail.com	Abdef1234\$
		NAU	andorra.nau1@hotmail.com	Abdef1234\$
		NAU	andorra.nau2@hotmail.com	Abdef1234\$
		NAU	andorra.nau3@hotmail.com	Abdef1234\$
4	Comoros	NFP	comoros.nfp@hotmail.com	Abdef1234\$
		NAU	comoros.nau1@hotmail.com	Abdef1234\$
		NAU	comoros.nau2@hotmail.com	Abdef1234\$
		NAU	comoros.nau3@hotmail.com	Abdef1234\$

Participants should visit the BCH' Training Site' (<https://bch.cbd.int>> Help> Training Site). Then log in using the assigned country user names and passwords.

Following the assigned role (NAU1, NAU2, etc.), each participant should identify information missing in the attached decision and is required to publish the relevant records. Then within the group, they should discuss the missing information and the relevant Cartagena Protocol articles.