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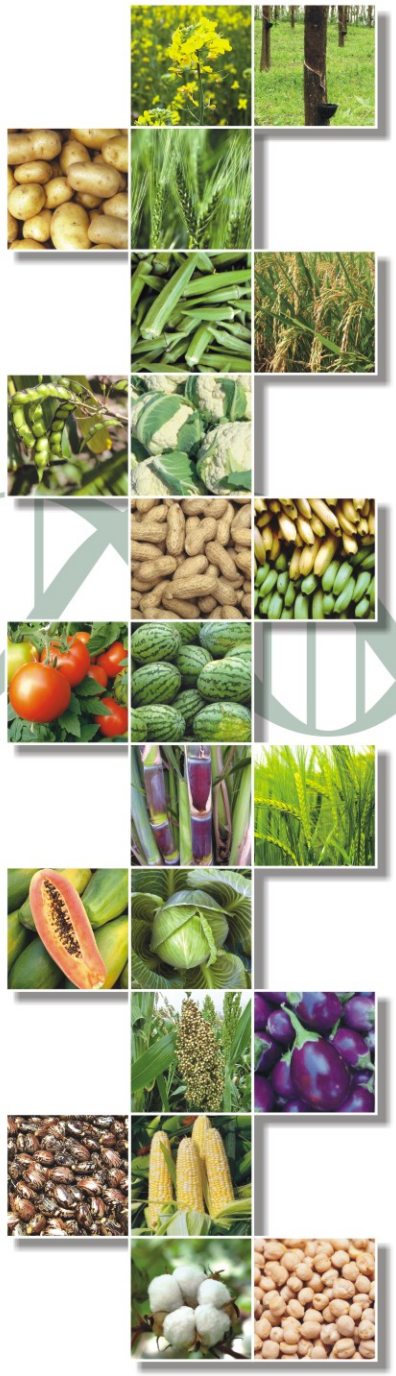
GENETICALLY ENGINEERED PLANTS IN THE PRODUCT DEVELOPMENT PIPELINE IN INDIA



RESULTS FROM A SURVEY CONDUCTED UNDER THE AUSPICES OF THE PHASE II CAPACITY BUILDING PROJECT ON BIOSAFETY

Ministry of Environment, Forest and Climate Change
Government of India

GENETICALLY ENGINEERED PLANTS IN THE PRODUCT DEVELOPMENT PIPELINE IN INDIA

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2016

Genetically Engineered Plants in the Product Development Pipeline in India
Results from a survey conducted under the auspices of the Phase II Capacity Building of Project on Biosafety

Prepared by
Ministry of Environment, Forest and Climate Change (MoEF&CC) and
in association with Centre for Environmental Risk Assessment-ILSI Research Foundation, Washington, USA under UNEP/GEF supported Phase II Capacity Building Project on Biosafety

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The results of this survey have also been published in the GM Crops & Food: Biotechnogies in Agriculture & Food Chain Journal of Taylor & Francis and can be accessed at http://www.tandfonline.com/doi/full/10.1080/21645698.2016.1156826

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1. Introduction

As part of the Phase II Capacity Building Project on Biosafety, the Ministry of Environment, Forest and Climate Change is interested in emerging issues that may impact the risk assessment and risk management functions of the Indian biosafety regulatory system. In order to proactively identify these, it is necessary to understand the nature and diversity of genetically engineered (GE) crops that may move to product commercialization within the next ten years (2014-2024). This report describes the results of a questionnaire designed to solicit information about public and private sector research and development (R&D) activities in plant biotechnology. It is the first comprehensive overview of the R&D pipeline for GE crops in India.

2. Materials And Methods

An electronic questionnaire was prepared to identify what GE crops and traits are currently under development or are anticipated to be developed within the next ten years (2014-2024) in India. It was distributed to approximately 1150 scientists from approximately 350 public and private sector organizations that are involved in plant breeding R&D in India. The questionnaire was comprised of two categories of questions: (1) general questions related to information about the respondent institution and its R&D activities; and (2) specific questions to provide information about specific transgenic plants currently under development.

In order to solicit accurate information respondents were not required to identify themselves and were informed that the results of all responses would remain confidential. This was in recognition of the fact that some organizations considered the information being sought as proprietary or market sensitive

3. Results

A total of 243 responses to the questionnaire were received by the closing date of May 1, 2014 which was a response rate of 23%. The questionnaire and aggregated results are provided in Annex I.

4. Summary

The results from the questionnaire indicate the following:

India has a very rich and innovative R&D pipeline. Respondents to the product pipeline questionnaire identified over 85 different plant species currently being used in experimental work, including plants used for food, livestock feed, fiber fuel and dietary or medicinal purposes. The ten most prevalent crops are presented in Figure 1 and a comprehensive list of all of the crop species identified by respondents is in Table 1. Trait variation was also found to be extensive, ranging from resistance traits for biotic stressors, to abiotic stress tolerances (e.g., drought, salt, heavy metals etc.) to truly novel nutritional, medicinal or metabolic phenotypes as seen in Figure 2. It includes the aggregated results of questions 9, 17, 25, 33 and 41.

Figure 1: The most prevalent crops in R&D programs by organizational category

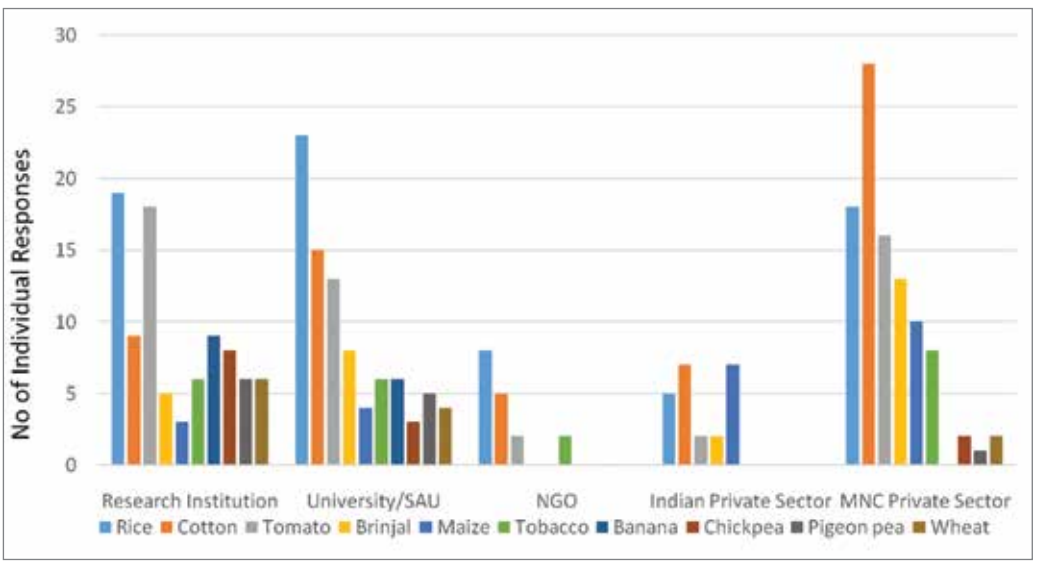
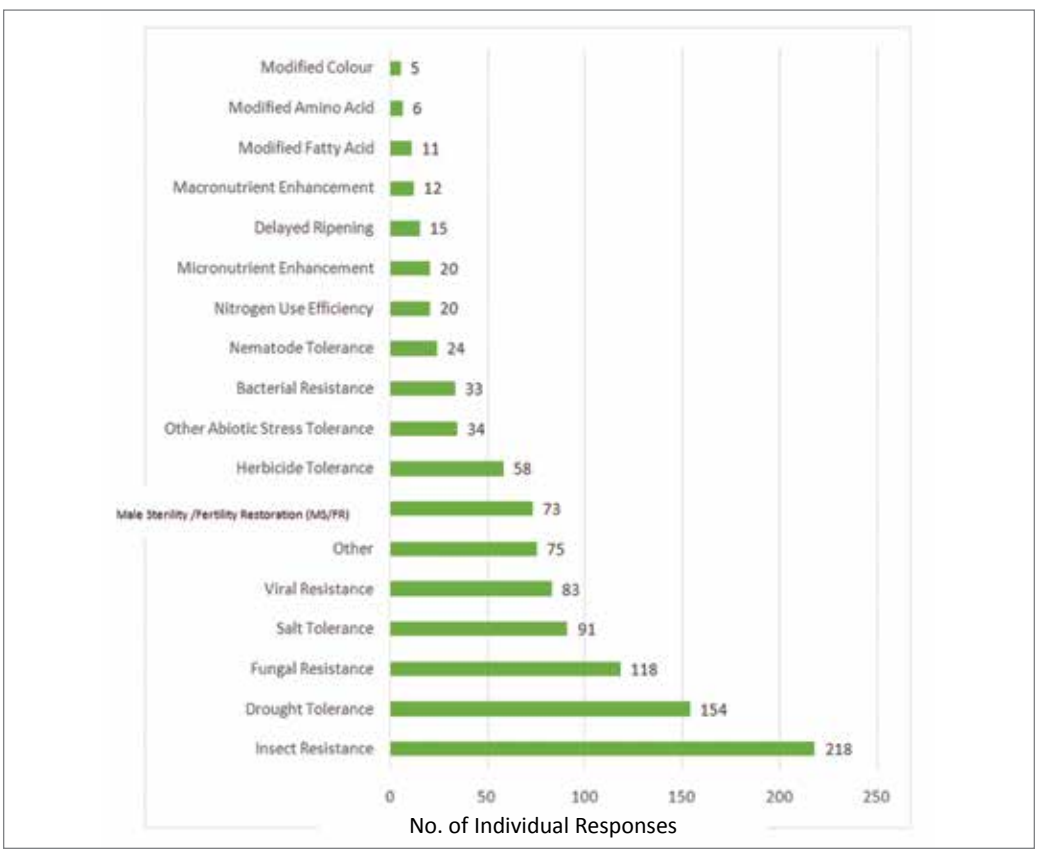


Table 1: A list of all crop species in the R&D pipeline as identified by respondents to the questionnaire
(The number in parentheses indicates number of respondents who listed the species)

Amorphaphallus (1)	Cenchrus (2)	*Lathyrus* (2)	Rice (73)
Apple (2)	*Centaurea depressa* (1)	Lucerne (1)	Rubber tree (3)
Arabidopsis (10)	Chickpea (14)	Maize (29)	Safflower (2)
Areca nut (2)	Chili (3)	Mango (1)	Scented rose (2)
Brassica caranata (1)	Cocoa (2)	Medicinal plants (1)	Sesame (2)
Brassica juncea (6)	Coconut (2)	*Melia* (1)	Sorghum (8)
Brassica napus (1)	Coffee (7)	Millet (4)	Soybean (5)
Brassica nigra (1)	Common bean (1)	Morus sp. (2)	Spinach (1)
Brassica rapa (3)	Cotton (64)	Mung bean (4)	Stevia (1)
Bacopa monnieri (4)	Cowpea (2)	Mustard (2)	Sugarcane (4)
Bamboo (2)	Cumin (1)	Ocimum sanctum (1)	Sunflower (5)
Banana (15)	Dendrobian (1)	Oilseed *brassicas* (1)	Sweet potato (2)
Black gram (3)	Dolichos (1)	Okra (12)	*Swertia spp.* (1)
Black pepper (3)	*Eleusine coracana* (3)	Onion (4)	*Switennia mehagony* (1)
Brahmi (3)	Eucalyptus (2)	*Panicum* (1)	Tea (5)
Brassica spp. (5)	Field pea (1)	Papaya (4)	Teak (1)
Brinjal (28)	Finger millet (1)	Pearl millet (2)	Tobacco (22)
Broccoli (2)	Foxtail millet (1)	*Pennisetum* (1)	Tomato (51)
Cabbage (2)	Garden pea (1)	*Phalaris minor* (1)	Triticale (1)
Capsicum (1)	Ginger (1)	*Phillanthus* (1)	Turmeric (1)
Cardamom (1)	*Gmelina* (1)	*Picorhhiza kurroa* (3)	Vegetables (1)
Cassava (3)	Green gram (3)	Pigeon pea (13)	Watermelon (6)
Castor (5)	Ground nut (6)	Pomegranate (1)	Wheat (12)
Casuarina (1)	Guava (2)	Poplar (2)	*Withania somnifera* (2)
Catharanthus (2)	Isagbol (1)	Potato (7)	
Cauliflower (3)	Jatropha (2)	Red pepper (1)	

Figure 1, Figure 2 and Table 1 demonstrate that Indian plant biotechnology R&D is being used to develop plant products that are relevant to Indian agriculture today but it is also forward looking. For example, there is significant research on traits that are relevant to mitigating the impacts of climate change on agriculture, which will be essential to ensuring that agricultural productivity is maintained and ultimately improved [1]. Productivity constraints in crops that are particularly relevant to smallholder farmers (e.g., pulses, millets) are also receiving significant attention, with important implications for improved food and nutrition security[2,3].

Figure 2. Aggregated responses for traits that are being studied in R&D programs

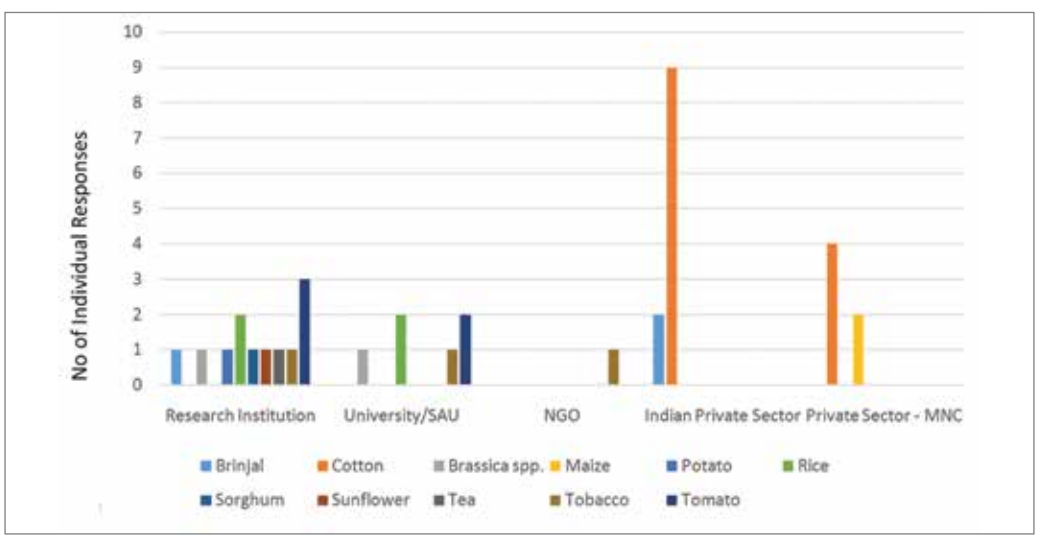


[1] Swaminathan MS and Kesavan PC. Agricultural research in an era of climate change. Agric Res 2012; 1(1): 3-11 • [2] National Academy of Agricultural Sciences. Role of millets in nutritional security of India. National Academy of Agricultural Sciences 2013; Policy Paper 66, New Delhi • [3] Erskine W, Sarker A. and Kumar S. Investing in lentil improvement toward a food secure world. Food Security 2011. 3(2):127-139

The majority of R&D projects reported in the questionnaire are early phase. For example, 80% of the respondents to Q10 indicated that their projects were limited to basic research, transformation and regeneration, or early phase event selection in contained conditions, and only 20% had progressed to event selection in confined field trials. Plant transformation is a commonly used and very important research tool, and it is likely that some of the R&D projects identified by respondents are experimental systems or proof-of-concept projects. This is important information as it emphasizes that the biosafety regulatory system must be responsive to all types of agricultural biotechnology research, be it for knowledge generation or product development. However, this may also be an indication that innovative R&D for product development is not advancing through to commercial product release. The reasons for this should be determined through a separate systematic study.

Thirty-five respondents indicated that they anticipated submitting applications for commercial release (i.e., cultivation and use in food and/or feed) of their GE crops by the end of 2016. Eighteen were from the public sector, 11 were Indian companies and eight were multi-national companies. Applications from the private sector are limited to brinjal, cotton and maize, whereas applications from the public sector encompass a much broader range of crops (Figure 3).

Figure 3. Applications for commercial approvals that respondents anticipate will be submitted to Indian regulatory authorities by the end of 2016



Public sector plant biotechnology R&D in India is very strong, with 73% of respondents self identifying from public sector research institutions, state agricultural or other universities. Of the 57 respondents who were identified as private sector, 78% were from Indian companies indicating that the domestic private sector is strongly represented in plant biotechnology R&D.

The majority of respondents (78-89%) expect India to be the first adopter of the GE crops they are developing. This is a strong indication that the GE plants under development by Indian scientists are intended for the Indian market, and that the R&D investment made in India should result in benefits for Indian farmers and consumers.

The results of the questionnaire also demonstrate a disconnection between respondents expectations for product delivery to farmers (i.e., commercial release of GE crops) and the reality of the time it actually takes to meet biosafety regulatory requirements in India. This means that many respondents are either unaware of what is required to demonstrate that a novel GE plant is as safe as its conventional counterpart, or have unrealistic expectations about how promptly products can advance from contained research, through Biosafety Research Level I (BRLI) and Biosafety Research Level II (BRLII) field trials[4] to approvals for cultivation and consumption. This deficit in understanding the staged pathway to product deployment needs to be addressed at the institutional level, at minimum by additional education and outreach. Product developers must have a realistic understanding of both the time and financial implications of meeting regulatory requirements in order to make informed decisions about whether project objectives can be achieved.

Internationally there is considerable experience as regards assessing the environmental and food safety of GE plants expressing insect resistance and/or herbicide tolerance traits, including published risk assessments conducted by competent authorities in many countries. While Figure 2 makes it clear that these traits are already common in Indian R&D programs, the Indian regulatory system must also prepare for the influx of new plants expressing new traits with which there is relatively less experience in India and elsewhere. This will be greatly facilitated if the development of tools and guidance needed to address these future challenges is initiated in the near term. Some suggestions are provided below.

[4] DBT and MoEF&CC. Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants 2008. Department of Biotechnology, Ministry of Science and Technology and Ministry of Environment, Forests and Climate Change, New Delhi.

Environmental risk and food safety assessment of GE crops are comparative exercises requiring specific kinds of information about the non-transformed host plant and its derived food and feed products. Biology and crop composition documents such as those published by the Organization for Economic Cooperation and Development[5] are very useful resources for this purpose. The Government of India has published biology documents for cotton, maize, okra and rice and is currently developing the same for chickpea, pigeon pea, sorghum, papaya, mustard, tomato, rubber and potato. The intent of these crop specific biology documents is to describe information that is directly relevant to environmental risk assessment in a format that is accessible to risk assessors and regulators. The document is an overview of pertinent biological information on the untransformed (i.e., conventional or non-transgenic) species that can be used as a reference to help define the baseline and scope for the conventional comparator against which transformed organisms will be compared in the risk assessment. As seen in Table 1, there are many other crop species that could potentially be submitted for regulatory permits and approvals in India and so additional biology documents will need to be prepared after a careful assessment that determines which of these new plant species are intended for eventual BRLI and BRLII confined field trials and commercialization (as some are being studied for basic research under contained conditions only). For less familiar crop species, it is likely that gaps in information essential for risk assessment (and hence the preparation of biology documents[6]) will need to be addressed through field research. For example, understanding the reproductive biology of the non-transformed plant species is essential to determine appropriate isolation practices so that confined field trials (e.g., BRLI and BRLII trials) of the experimental, transgenic plants can be effectively managed. Similarly, it will be necessary to identify important food and feed nutrients, as well as anti-nutrients, toxins or allergens that occur naturally in those crop species that will be used for food and/or feed so that any changes in these that lie outside of the normal range of variation can be identified and evaluated as part of the safety assessment process.

[5] See http://www.oecd.org/env/ehs/biotrack/consensus documents for the work on harmoni sation of regulatory over sight in biotechnology.htm and http://www.oecd.org/env/ehs/biotrack/consensus documents for the work on the safety of novel foods and feeds.htm.

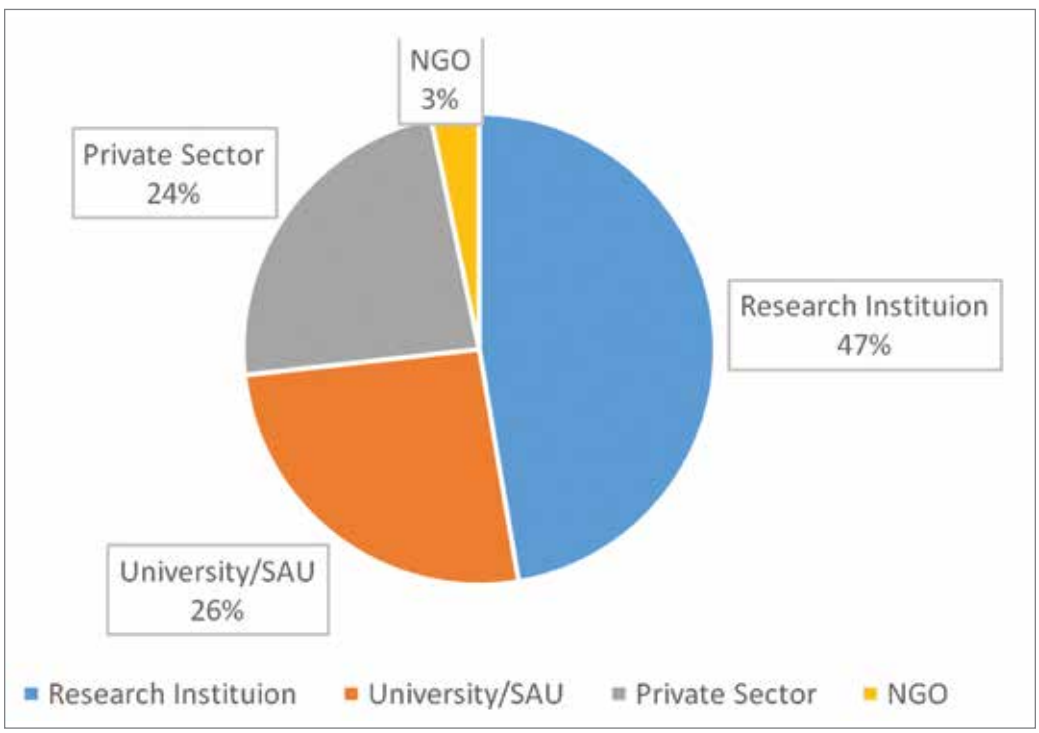
[6] Refer to the OECD publication Points to Consider for Consensus Documents on the Biology of Cultivated Plants (ENV/JM/MONO(2006)1). The document can be accessed from http://www.oecd.org/env/ehs/biotrack/consensusdocumentsfortheworkonharmonisationofregulatoryoversightinbiotechnologyfacilitatingharmonisation.htm

Annex I: Questionnaire And Results

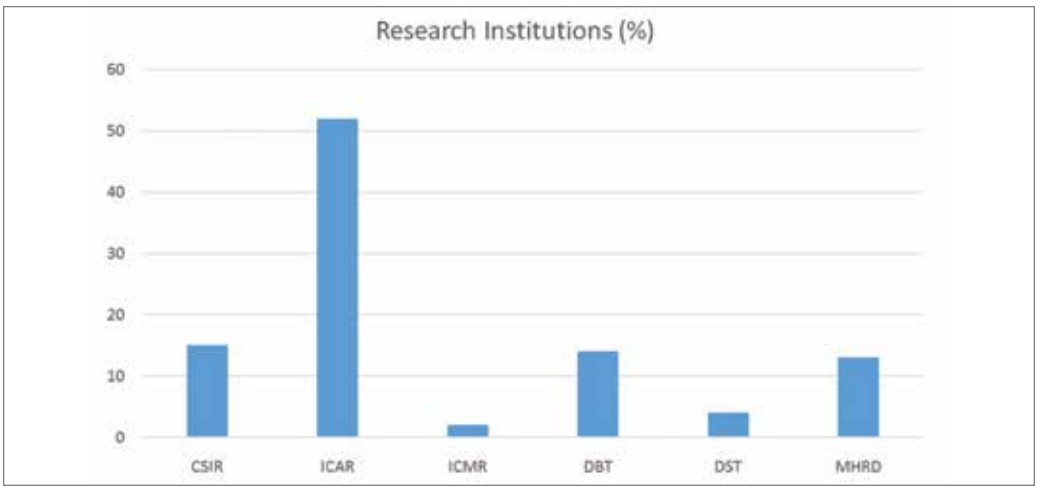
The results for each question are summarized below. The number of respondents that answered or skipped each question is indicated in parenthesis after each question (answered/skipped)

A. General Questions

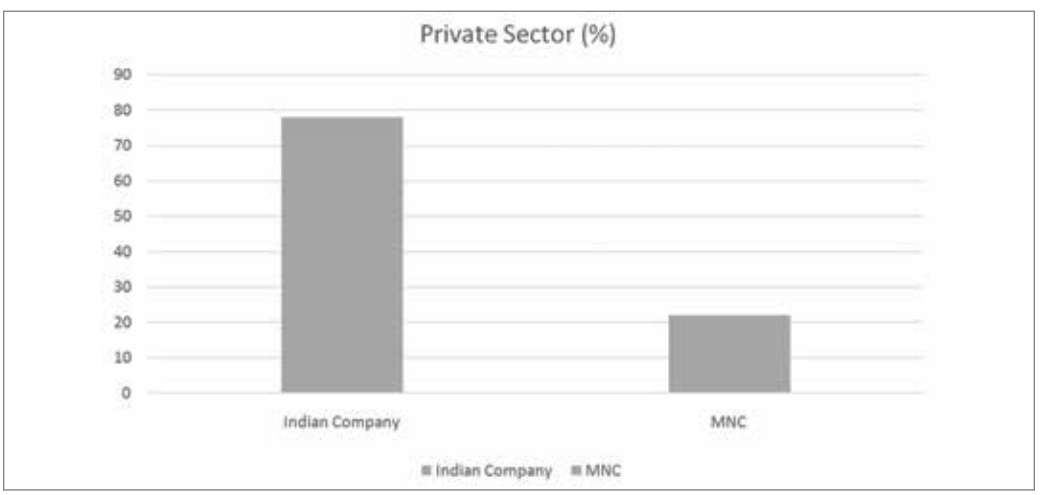
Q1. Please choose the item that best describes your organization (243/0)



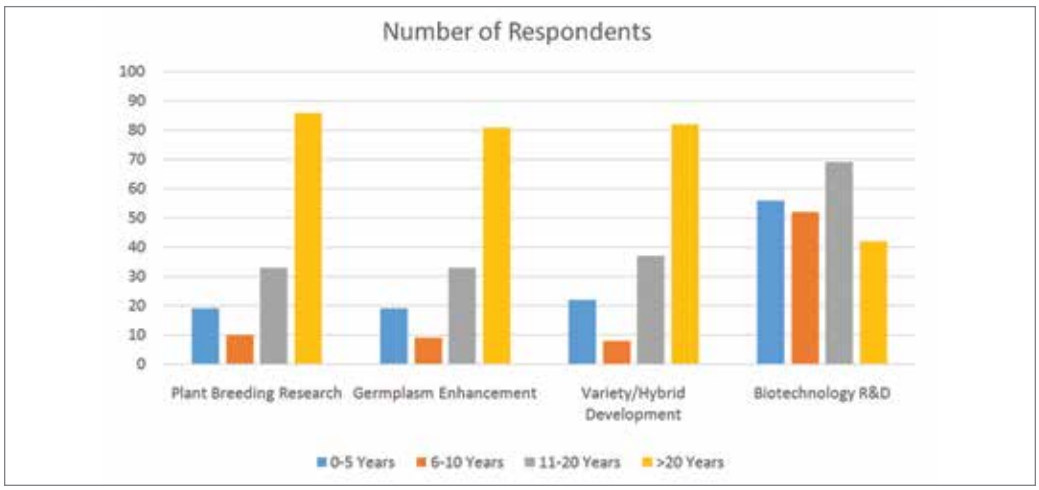
Q2. If you answered "Research Institution" in question 1, please indicate if you are under any one of the following agencies (104/139)



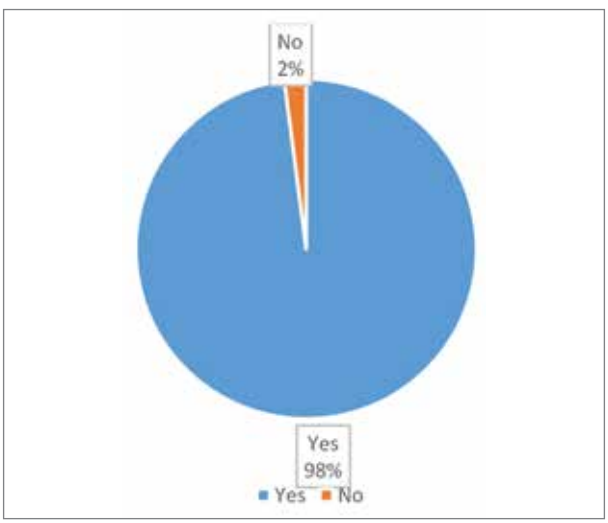
Q3. If you answered "Private Sector" in question #1, please indicate if you are under one of the following companies (59/184)



Q4. Indicate how many years your organization has been involved in: (243/0)



Q5. Does your organization have an Institutional Biosafety Committee? (243/0)

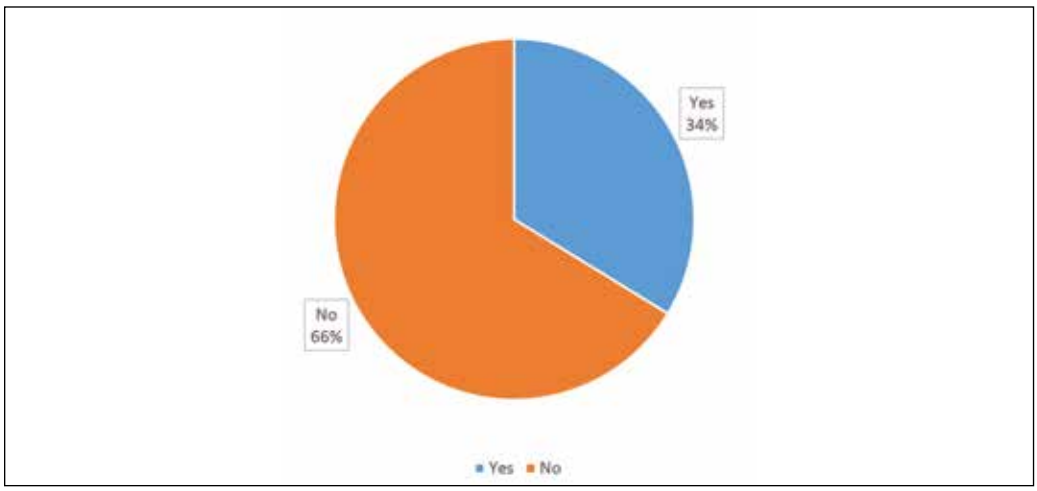


Q6. Please indicate the crop species that are currently part of biotechnology R&D programs at your organization: (243/0)

Each respondent was asked toprovide information for up to five crop species, listed in the questionnaire as Crop Species 1-5. The table below includes all of the crop species identified in each of the five categories. The number of respondents for each crop species/category is indicated in parentheses (e.g., under Crop 1, five respondents listed *Arabidopsis*). Of the 243 respondents to the questionnaire, 94% provided details for Crop Species 1; 58% for Crop Species 2; 45% for Crop Species 3; 22% for Crop Species 4 and 22% for Crop Species 5.

Crop Species 1	Crop Species 2	Crop Species 3	Crop Species 4	Crop Species 5
Apple (1)	Tomato (15)	Rose (1)	Rose (1)	Rice (1)
Arabidopsis (5)	Wheat (5)	Sadabahar(1)	Safflower (1)	Sorghum (1)
Brassica juncea (5)	*Arabidopsis* (1)	Safflower (1)	Sunflower (1)	Soybean (3)
Banana (2)	Arecanut (2)	Soybean (1)	*Swertia sp.* (1)	Stevia (1)
Black pepper (3)	*B. rapa* (3)	Sweet potato (1)	Teak (1)	Sugarcane (1)
Brahmi (4)	Bamboo (1)	Tobacco (5)	Tobacco (1)	Sweet potato (1)
Brinjal (8)	Banana (6)	Tomato (14)	Tomato (11)	Tea (1)
Bunchgrass (1)	Brahmi (1)	Watermelon (2)	*Triticale* (1)	Tobacco (9)
Cabbage (1)	Brinjal (9)	Wheat (2)	*Turmeric* (1)	Tomato (6)
Cassava (1)	Broccoli (1)	*Amorphaphaullus* (1)	Watermelon (1)	Watermelon (3)
Castor (2)	Cabbage (1)	Apple (1)	Wheat (4)	Wheat (1)
Cenchrus (2)	Capsicum (1)	*B. nigra* (1)	Indian ginseng (2)	*Arabidopsis* (2)
Chickpea (9)	Casaurina (1)	Bamboo (1)	*Arabidopsis* (2)	*B. napus* (1)
Coconut (2)	Castor (2)	Banana (3)	*B. carinata* (1)	Banana (3)
Coffee (4)	Cauliflower (1)	Black gram (1)	Banana (1)	Black gram (1)
Cotton (44)	Cornflower (1)	*Brassica* (1)	Black gram (1)	*Brassica* (2)
Eucalyptus (2)	Chickpea (1)	Brinjal (2)	Brinjal (8)	Brinjal (1)
Foxtail millet (1)	Chili (1)	Cauliflower (2)	Broccoli (1)	Cassava (2)
Ground nut (2)	Common bean (1)	Chickpea (2)	Cardamom (1)	Castor (1)
Jatropha (2)	Cotton (12)	Chili (2)	Chickpea (2)	Cotton (2)
Maize (6)	Finger millet (2)	Cocoa (2)	Cowpea (2)	Cumin (1)
Medicinal plants (1)	Ginger (2)	Cotton (6)	*Dendrobian* (1)	Garden pea (1)
Mulberry (1)	Green gram (2)	Dolichos (1)	*Gmelina* (1)	Guava (1)
Tulsi (1)	Ground nut (1)	Field pea (1)	Groundnut (2)	Maize (1)
Papaya (1)	Guava (1)	Green gram (1)	Isagbol 1	Melia (1)
Potato (4)	Kutki (1)	Ground nut (1)	Kutki (3)	Millet (1)
Ragi (1)	*Lathyrus* (1)	Mahogany (1)	*Lathyrus* (1)	Mustard (1)
Rice (39)	Maize (8)	Maize (7)	Lucerne (1)	Okra (2)
Rubber tree (3)	*Morus sp.* (1)	Millet (4)	Maize (2)	*Phyllanthus* (1)
Sadabahar(1)	Mung bean (3)	Okra (2)	Mango (1)	Pigeon pea (1)
Sesame (1)	Mustard (1)	Onion (3)	Millet (1)	Rice (2)
Sorghum (7)	Okra (3)	Panicum (1)	Mung bean (1)	Sesame (1)
Soybean (1)	*Pennisetum* (1)	Papaya (3)	Okra (5)	Spinach (1)
Sugarcane (4)	Pigeonpea (8)	Pearl millet (1)	Onion (1)	Sunflower (3)
Sunflower (1)	Poplar (1)	Pigeon pea (3)	Pomegranate (1)	Tea (1)
Tea (3)	Potato (1)	Potato (2)	Poplar (1)	Tobacco (1)
Tobacco (6)	Rice (20)	Rice (11)	Red pepper (1)	Tomato (5)

Q7. Do you anticipate that a new crop species (other than those listed for Crop Species 1-5) will be used in biotechnology R&D programs at your organization within the next 3 years?If "Yes", please indicate which species and traits are likely to be examined(243/0)

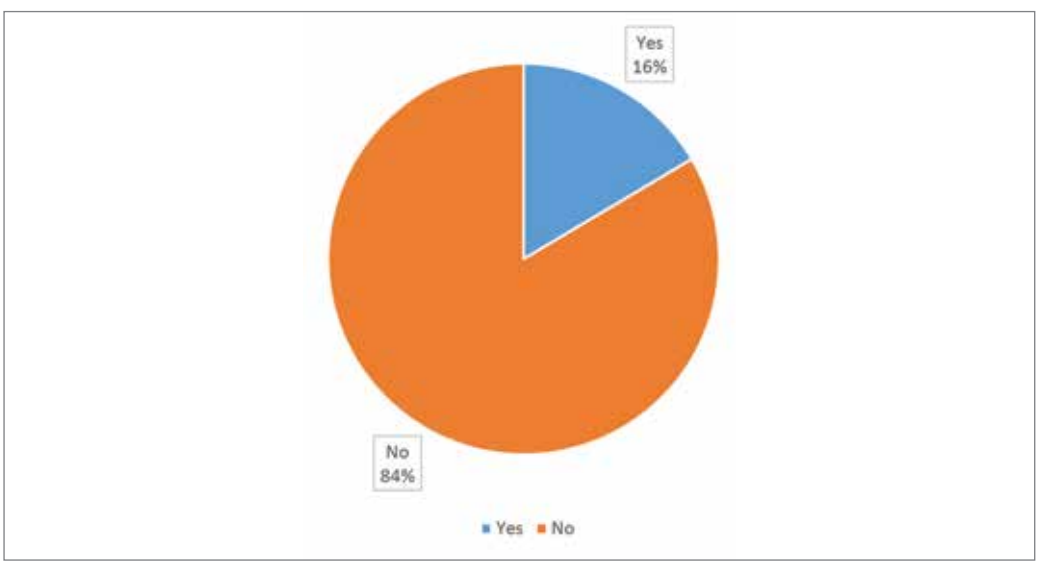


The crops species indicated by respondents are listed below. The number of respondents for each crop species is indicated in parentheses.

Ailanthus (1)	Cabbage (2)	Foxtail millet (2)
Apple rootstock (2)	Canola (1)	Fruits (2)
Aromatic plants (1)	Cardamom (1)	Grasses (2)
Banana (1)	Cauliflower (3)	Ground nut (2)
Bitter gourd (1)	Cereals (2)	Hot pepper (1)
Black gram (2)	Chickpea (2)	*Lathyrus* (1)
Bottle gourd (1)	Chili (4)	Lentil (1)
Brassica sp. (3)	Finger millet (1)	Maize (5
Brinjal (2)	Flowers (3)	Medicinal plants (2)

Melon (1)	Field pea (1)	Soybean (2)
Millet (1)	Plantation crops (2)	Sugarbeet (1)
Mung bean (1)	Pomegranate (2)	Sugarcane (4)
Mustard (4)	Potato (3)	Sunflower (1)
Okra (1)	Pulses (3)	Tomato (3)
Onion (1)	Rice (6)	Tuberose (2)
Ornamental crops (1)	Sesame (2)	Vegetable crops (5)
Papaya (4)	*Solanum chacoense* (1)	*Vigna sp.* (1)
Parthenium argentatum (1)	*Solanum sparsipilum* (1)	Watermelon (1)
Pearl millet (1)	*Solanum spegazzinii* (1)	Wheat (3)
Pigeon pea (6)	Sorghum (4)	*Withania somnifera* (1)

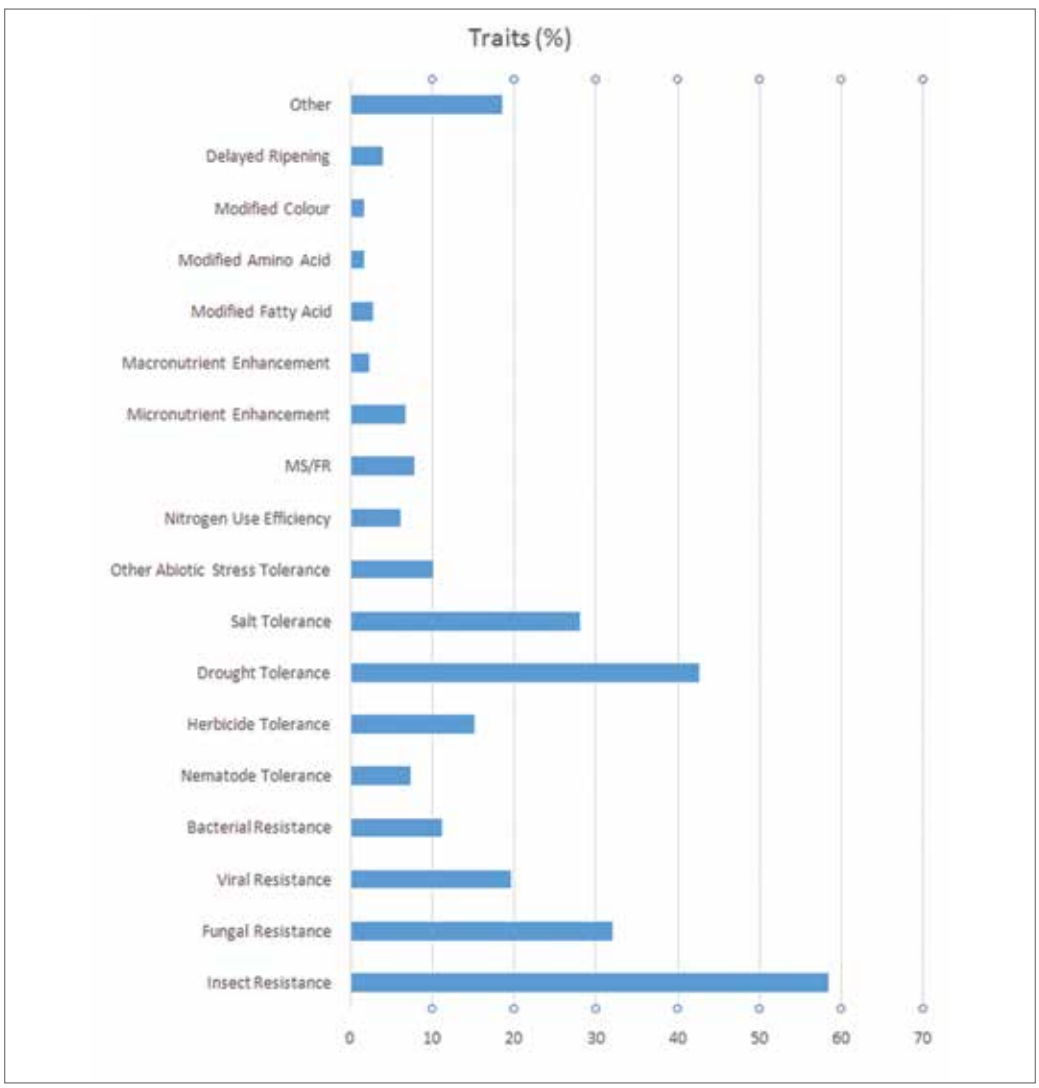
Q8. Are there transgenic plant materials from discontinued research programs currently stored at your institution? (243/0)



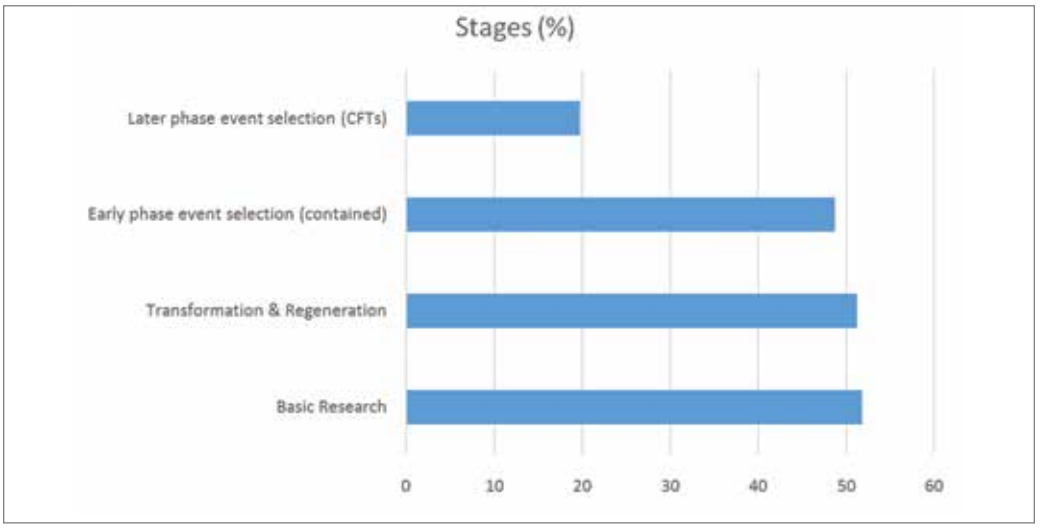
B. Product-Specific Questions

CROP SPECIES 1

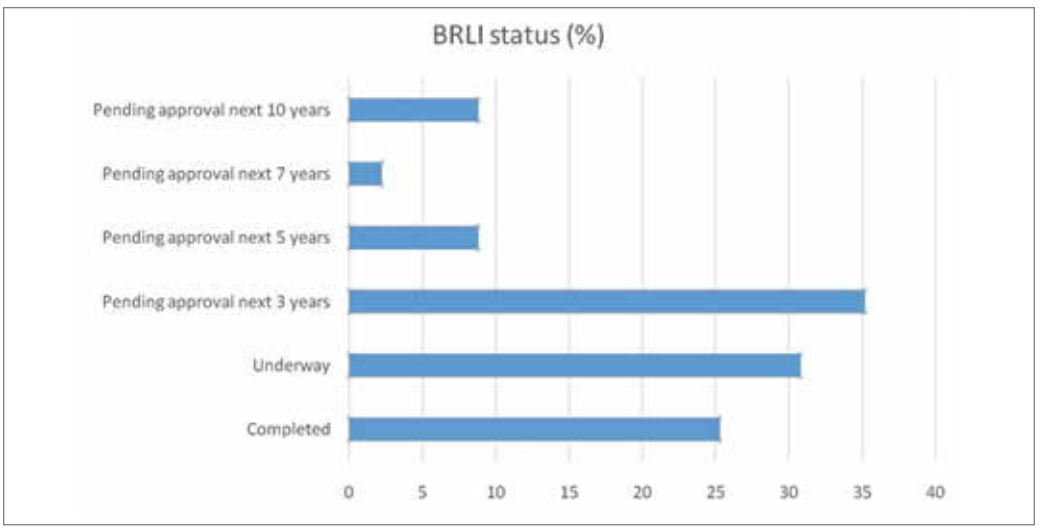
Q9. Please indicate which trait or traits are being studied (select as many as apply): (178/65)



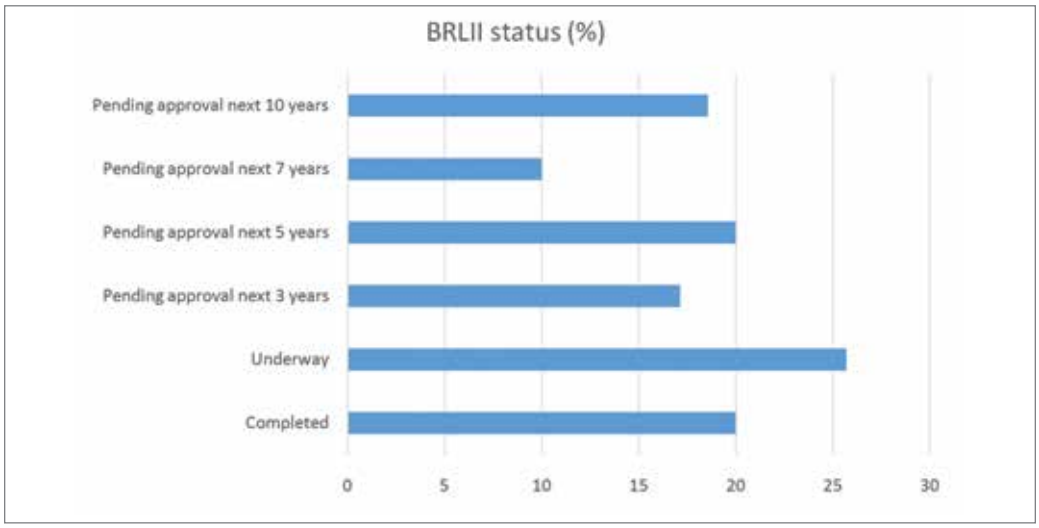
Q10. Which stage(s) of product development have been completed to date? (162/81)



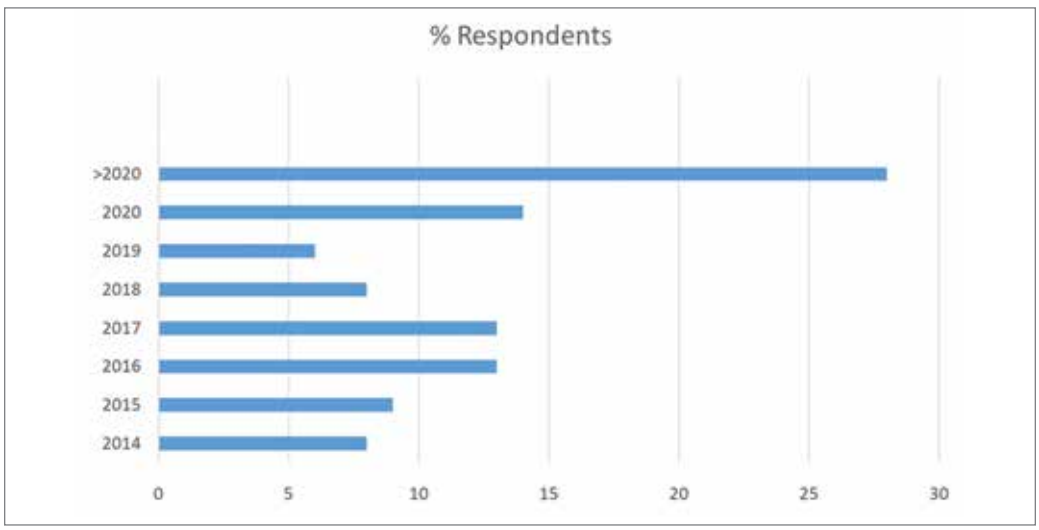
Q11. Which stage of BRLI trials have been completed to date? (91/152)



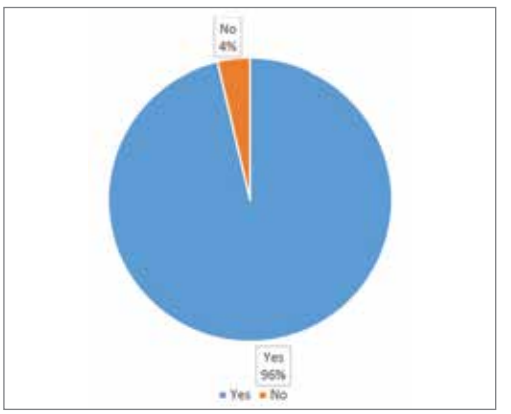
Q12. Which stage of BRLII trials have been completed to date? (70/173)



Q13. When do you anticipate submitting this product for commercial approval? (127/116)



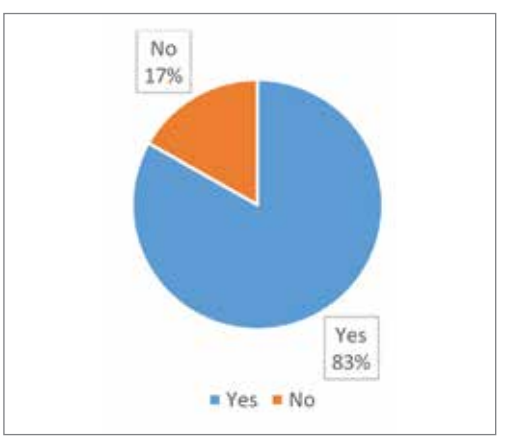
Q14. Has this product been approved in any other countries? (148/95)



Q15. If yes, please indicate which countries. (37/206)

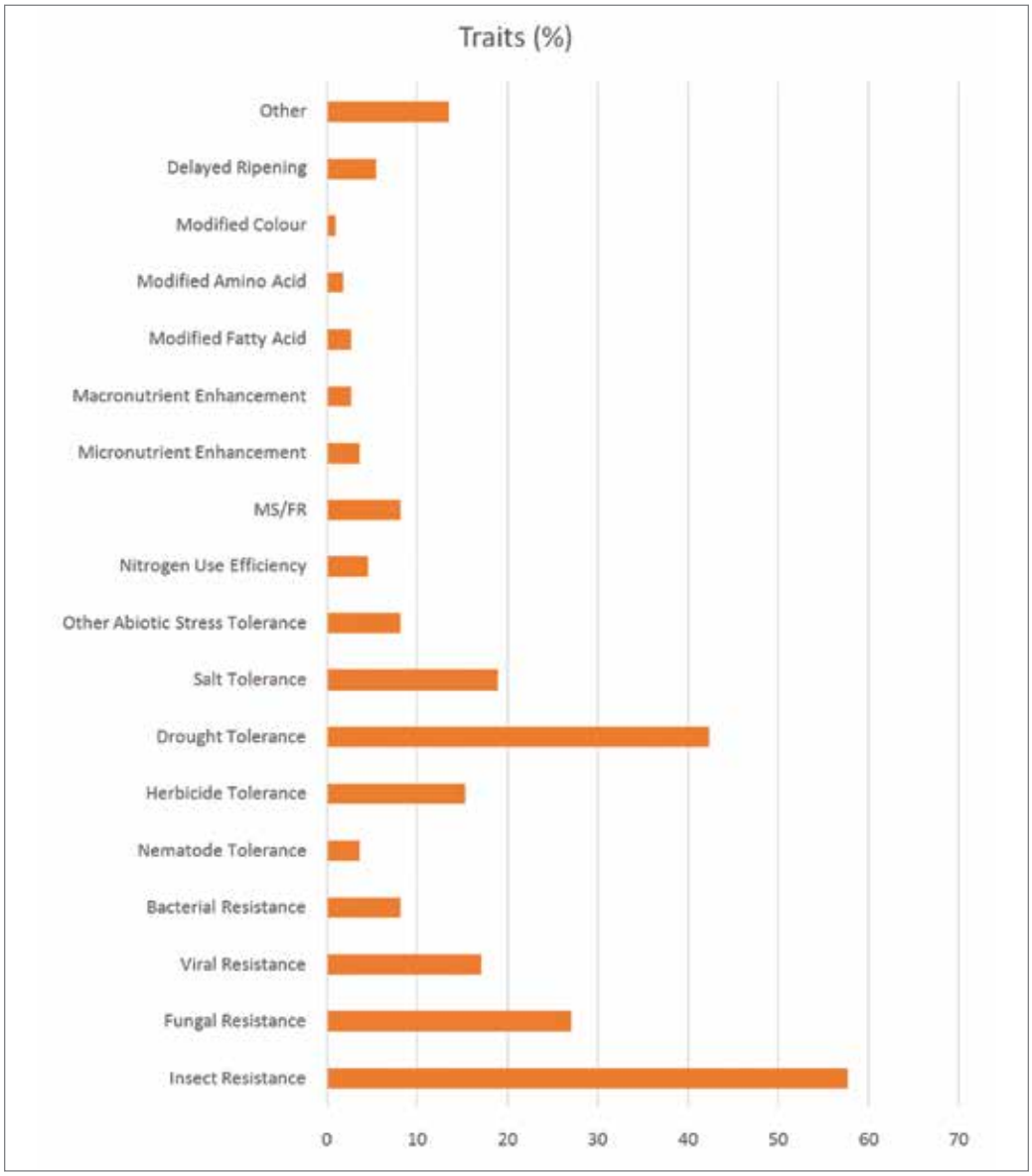
Argentina	Colombia	Japan	Spain
Australia	European Union	Korea,	Switzerland
Bangladesh	Germany	Mexico	Taiwan
Brazil	Honduras	New Zealand	USA
Canada	Indonesia	Philippines	Vietnam
China	Iran	South Africa	

Q16. If no, do you expect it to be approved in India first? (113/130)

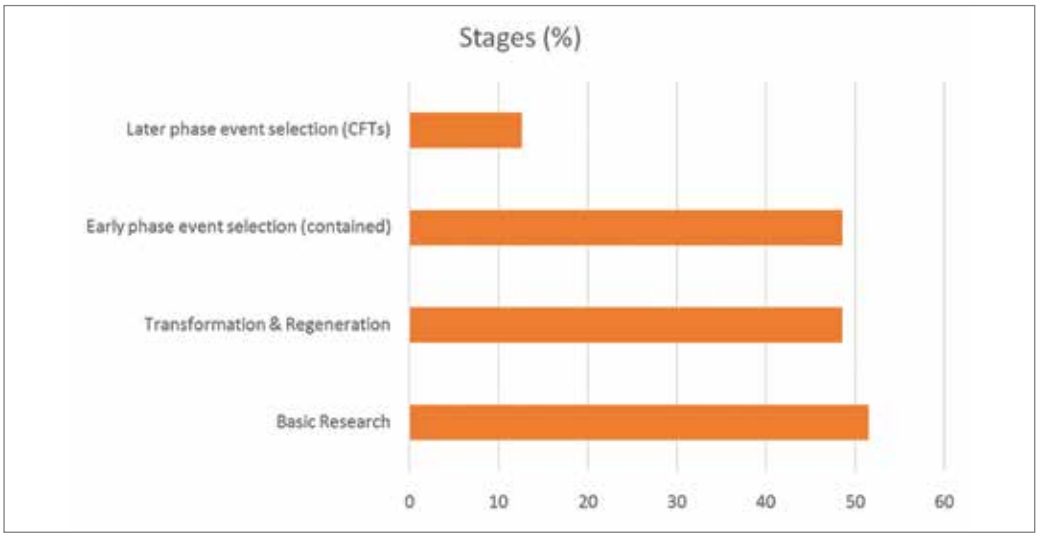


CROP SPECIES 2

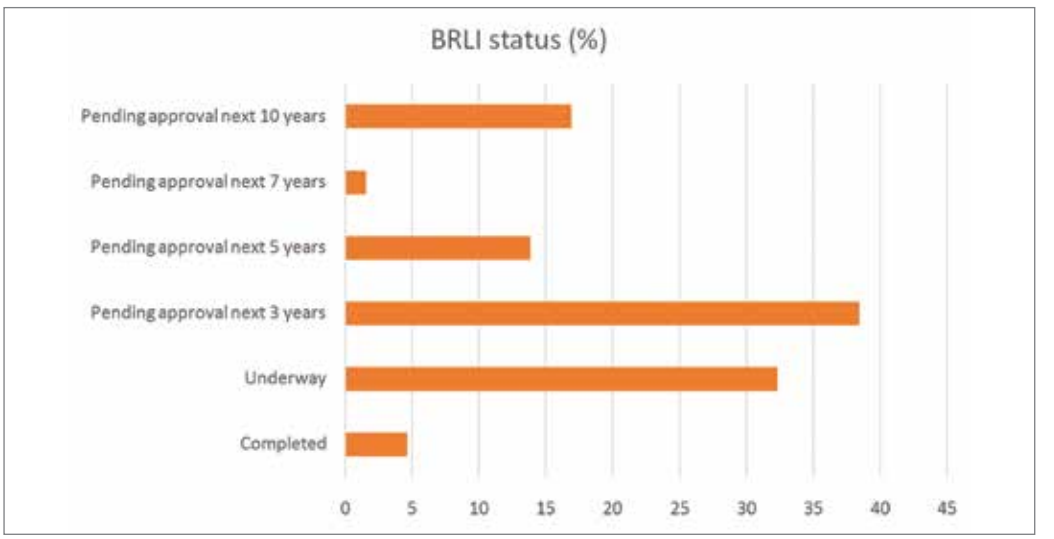
Q17. Please indicate which trait or traits are being studied (select as many as apply): (111/132)



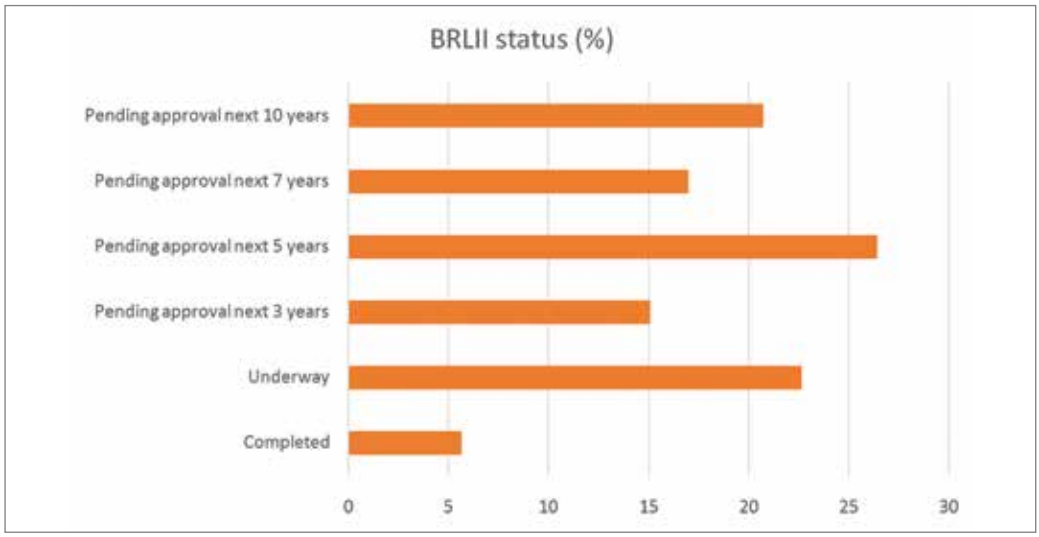
Q18. Which stage(s) of product development have been completed to date? (103/140)



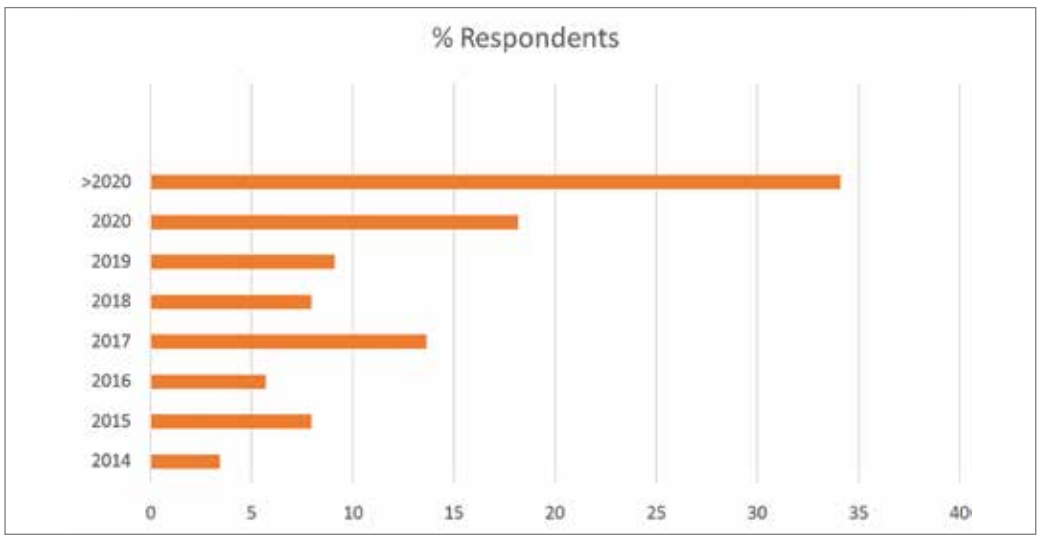
Q19. Which stage of BRLI trials have been completed to date? (65/178)



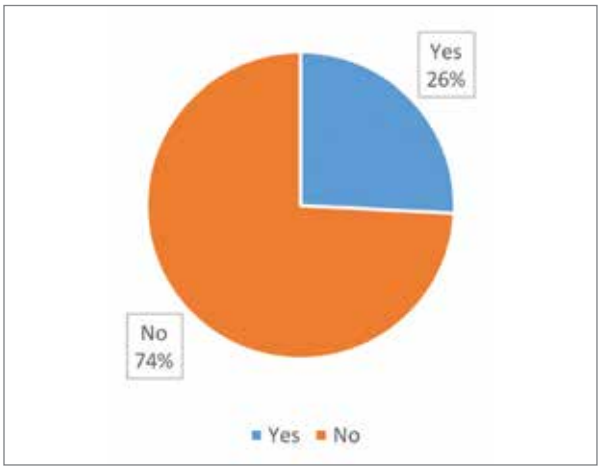
Q20. Which stage of BRLII trials have been completed to date? (53/190)



Q21. When do you anticipate submitting this product for commercial approval? (88/155)



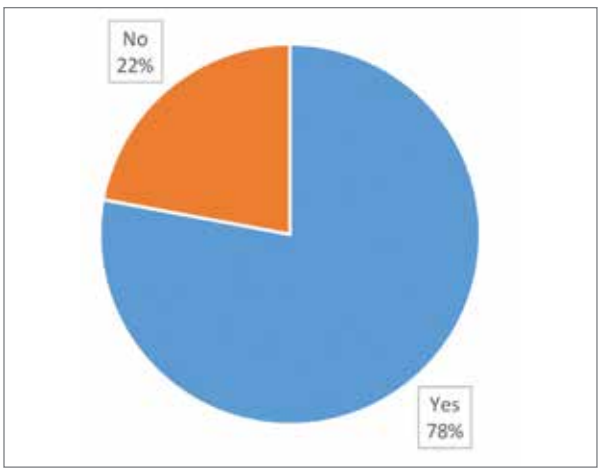
Q22. Has this product been approved in any other countries? (93/150)



Q23. If yes, please indicate which countries. (24/219)

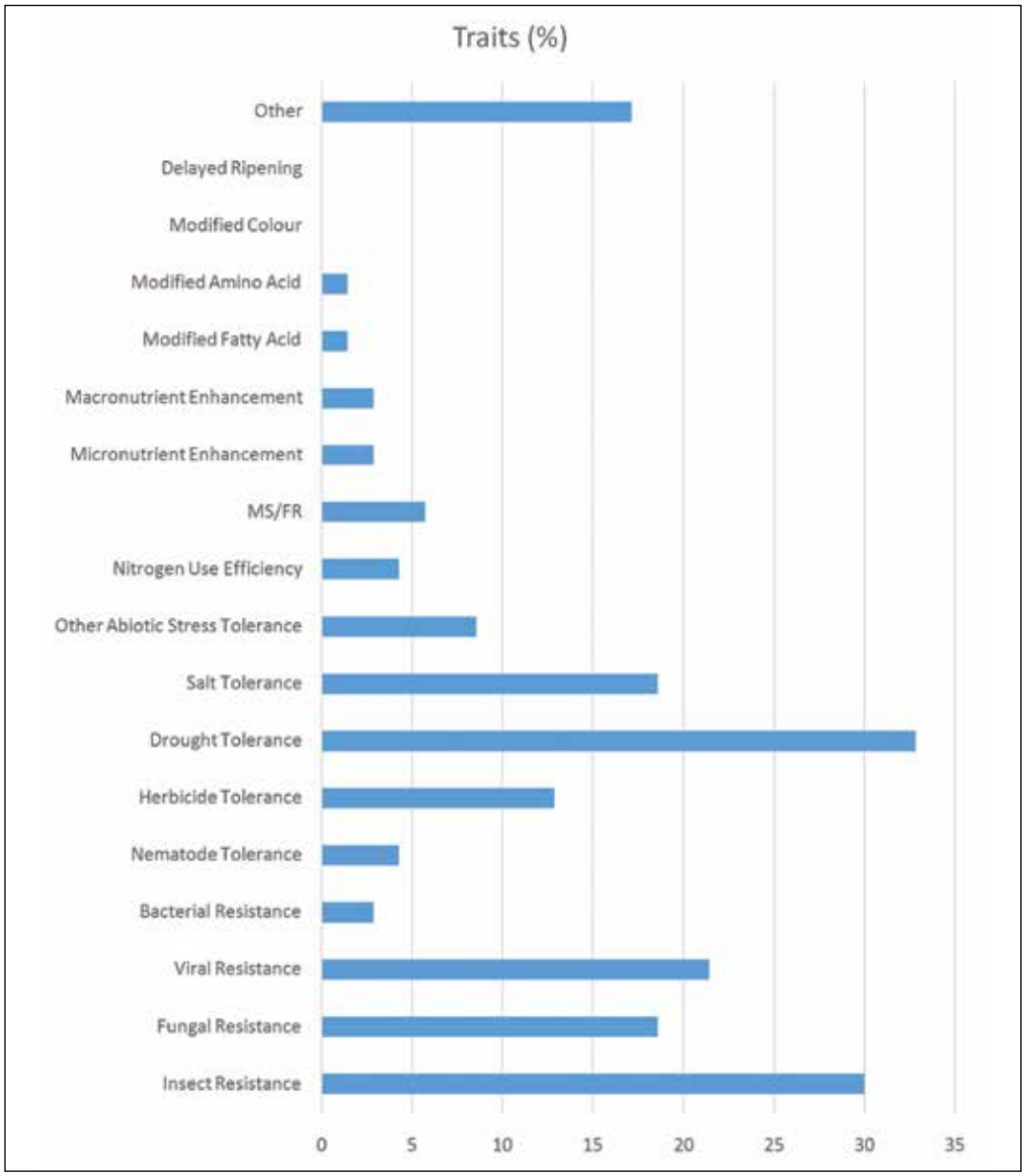
Argentina Australia	Bangladesh Brazil	China Philippines USA

Q24. If no, do you expect it to be approved in India first? (77/166)

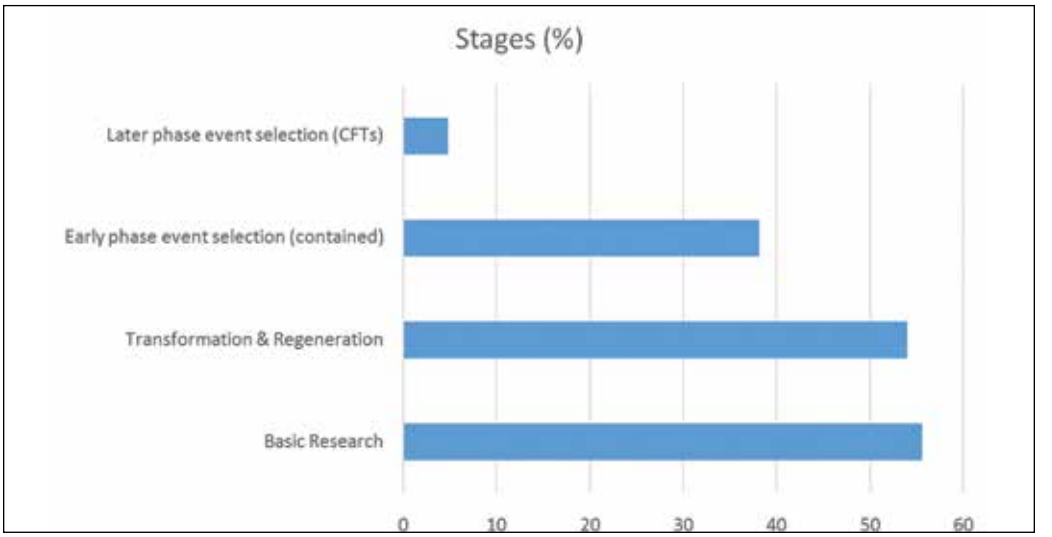


CROP SPECIES 3

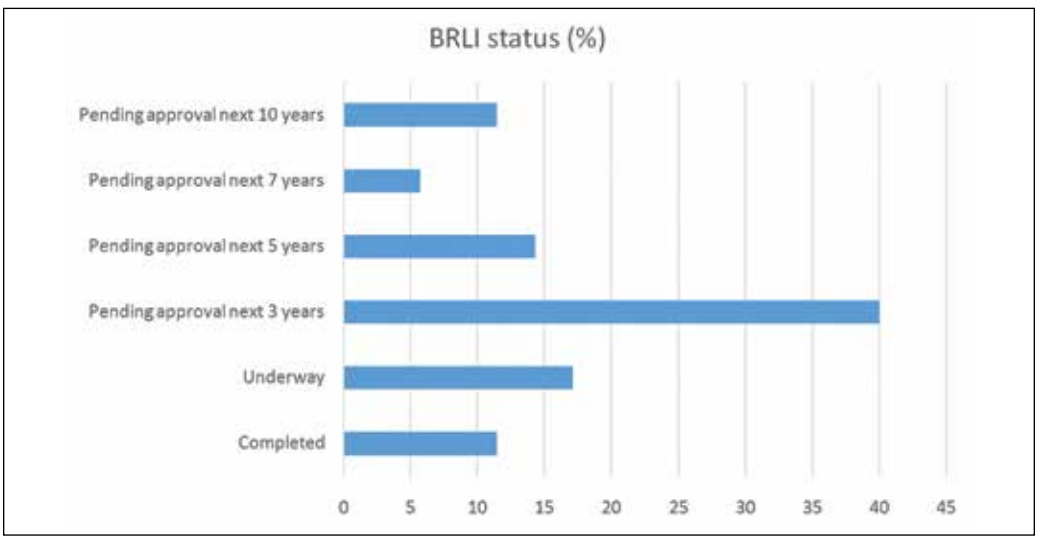
Q25. Please indicate which trait or traits are being studied (select as many as apply): (70/173)



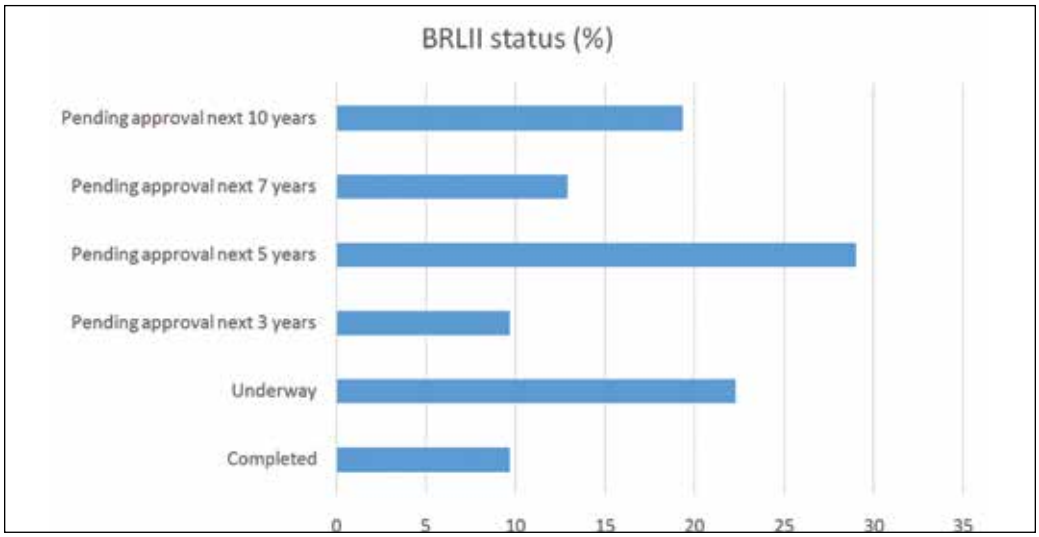
Q26. Which stage(s) of product development have been completed to date? (63/180)



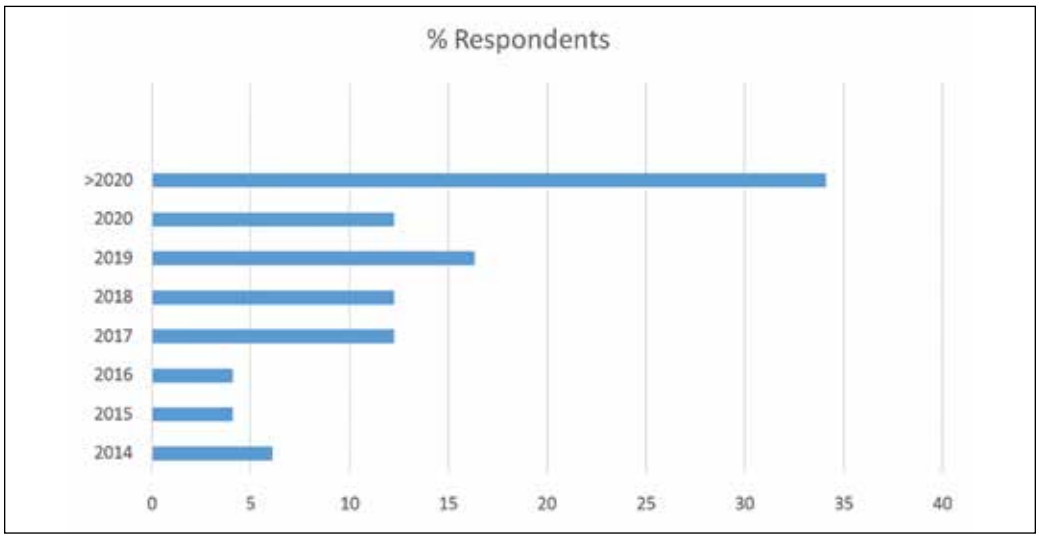
Q27. Which stage of BRLI trials have been completed to date? (35/208)



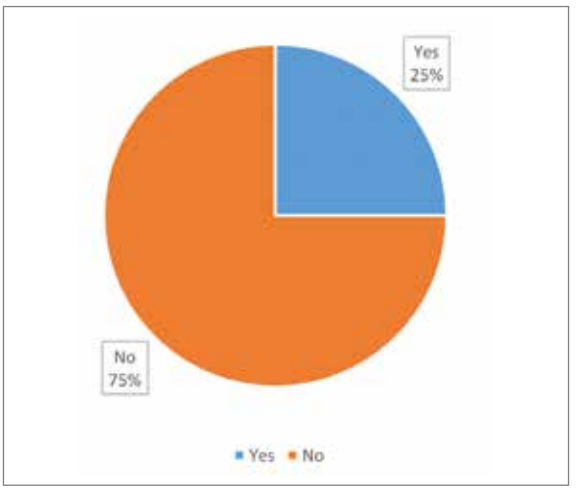
Q28. Which stage of BRLII trials have been completed to date? (31/212)



Q29. When do you anticipate submitting this product for commercial approval? (49/194)



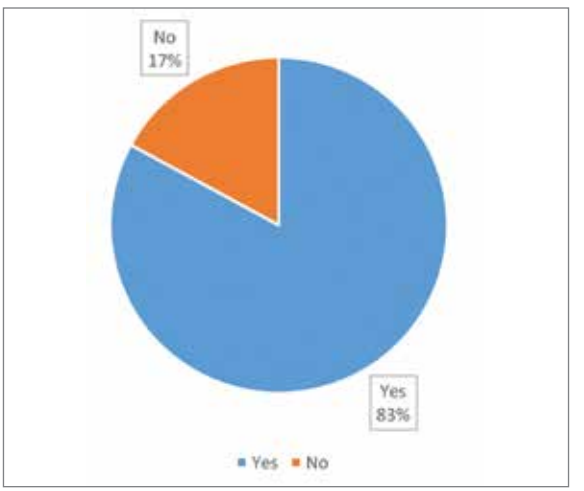
Q30. Has this product been approved in any other countries? (52/191)



Q31. If yes, please indicate which countries. (14/229)

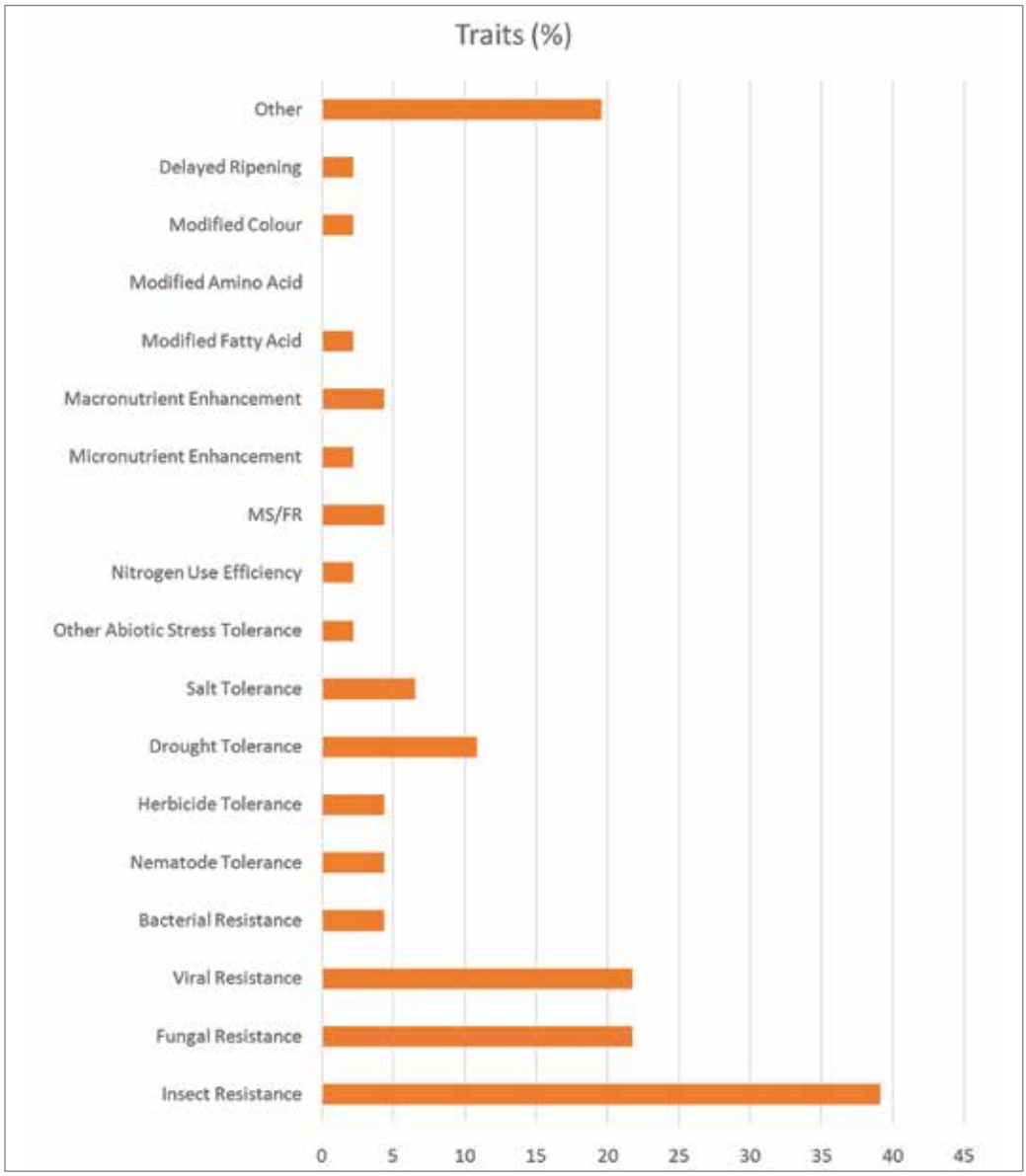
Argentina	China	USA
Bangladesh	European Union	

Q32. If no, do you expect it to be approved in India first? (41/202)

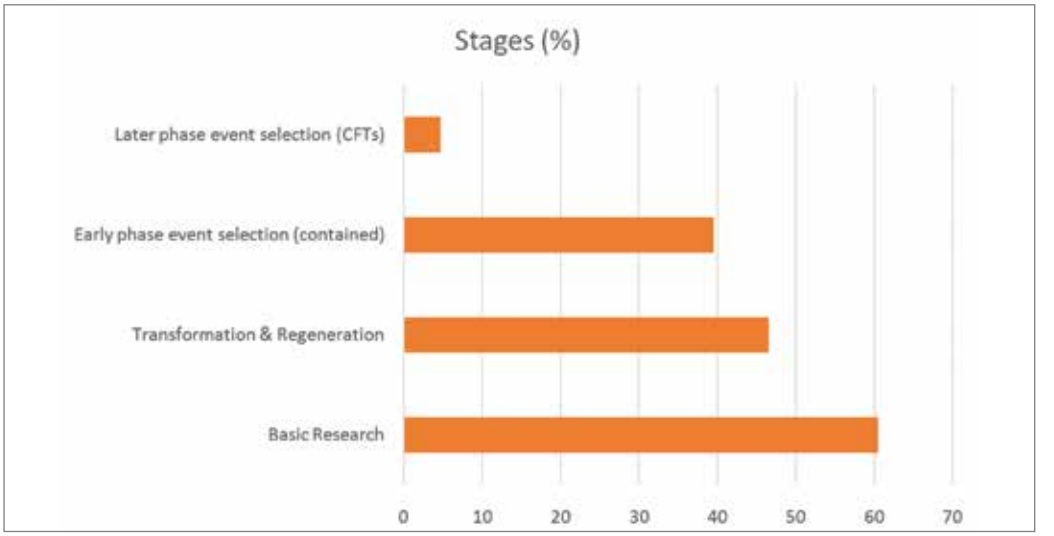


CROP SPECIES 4

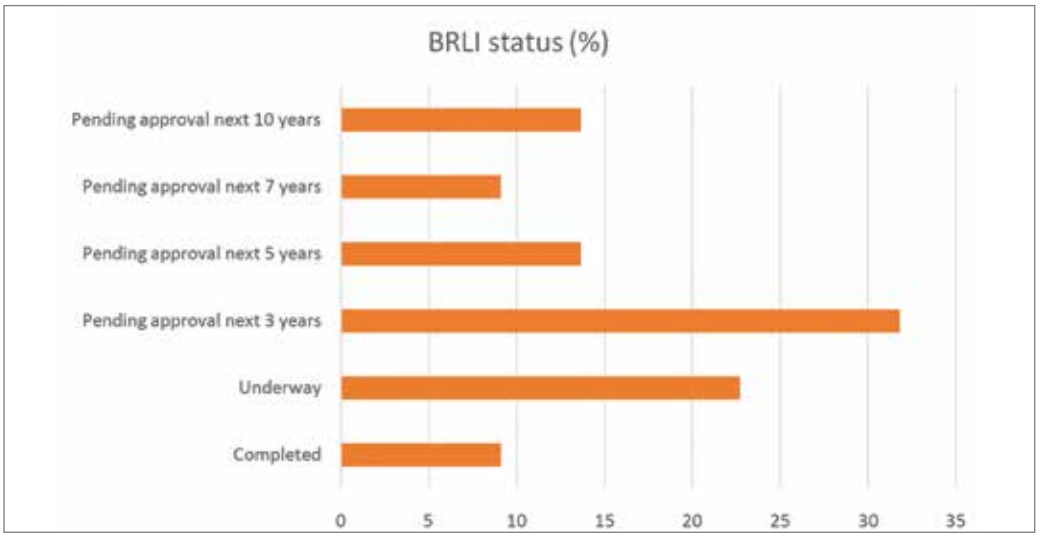
Q33. Please indicate which trait or traits are being studied (select as many as apply): (46/197)



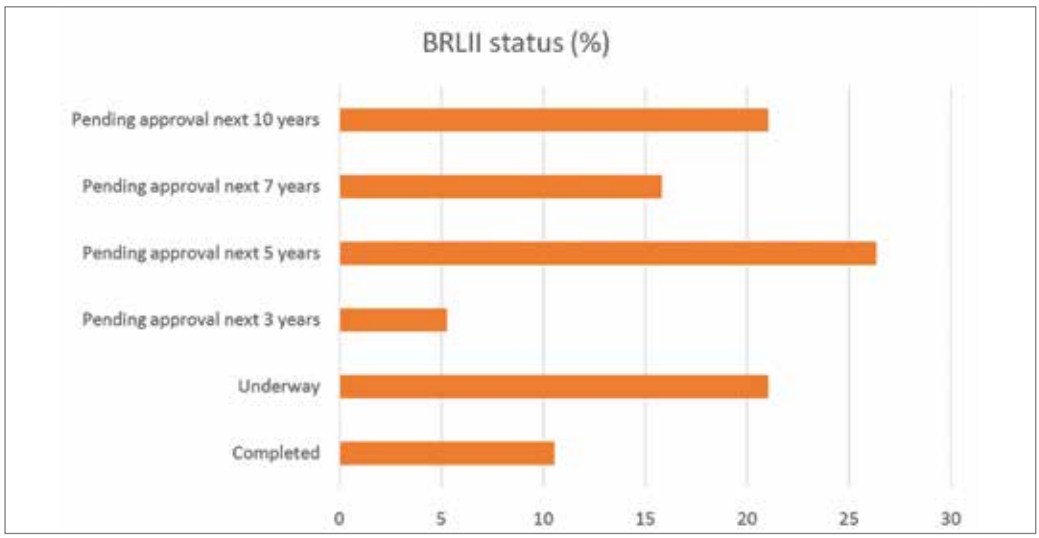
Q34. Which stage(s) of product development have been completed to date? (43/200)



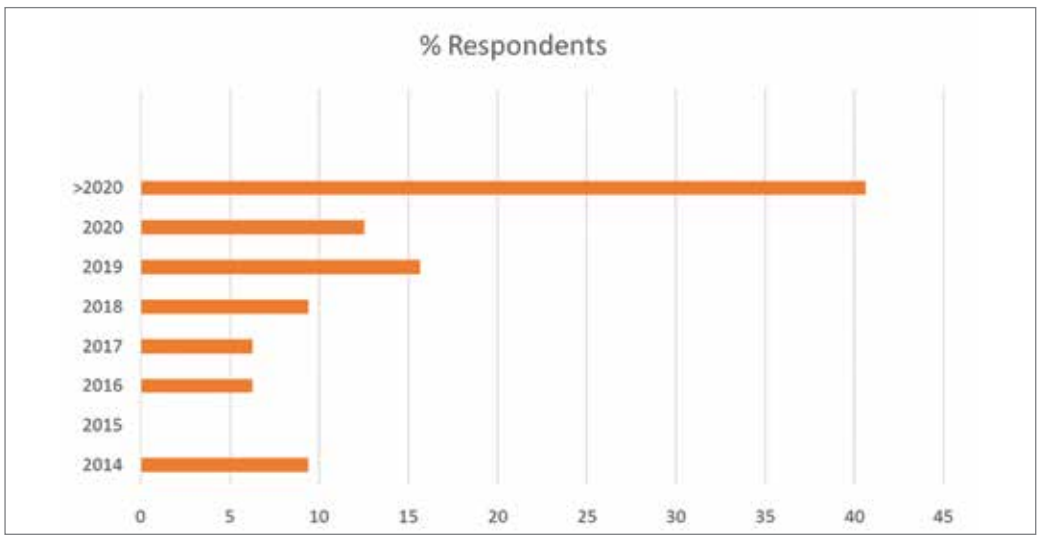
Q35. Which stage of BRLI trials have been completed to date? (22/221)



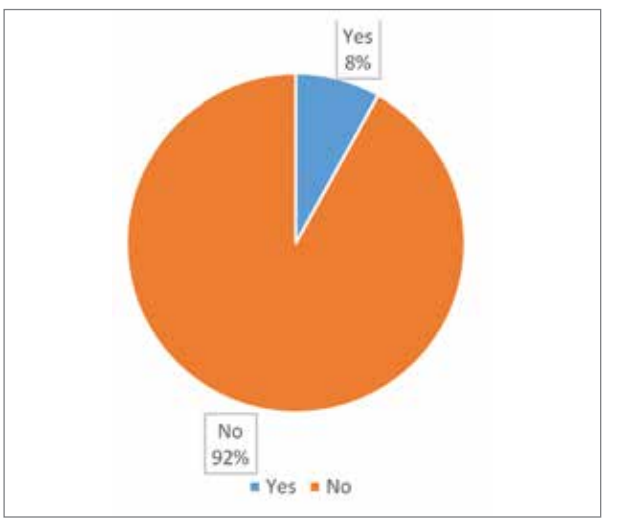
Q36. Which stage of BRLII trials have been completed to date? (19/224)



Q37. When do you anticipate submitting this product for commercial approval? (32/211)



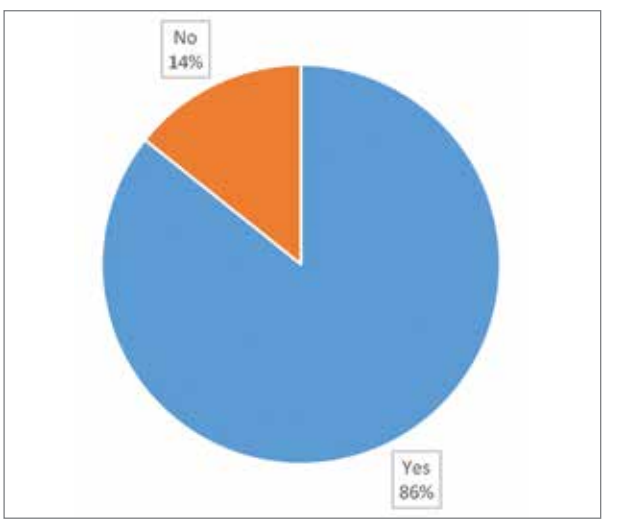
Q38. Has this product been approved in any other countries? (37/206)



Q39. If yes, please indicate which countries. (3/240)

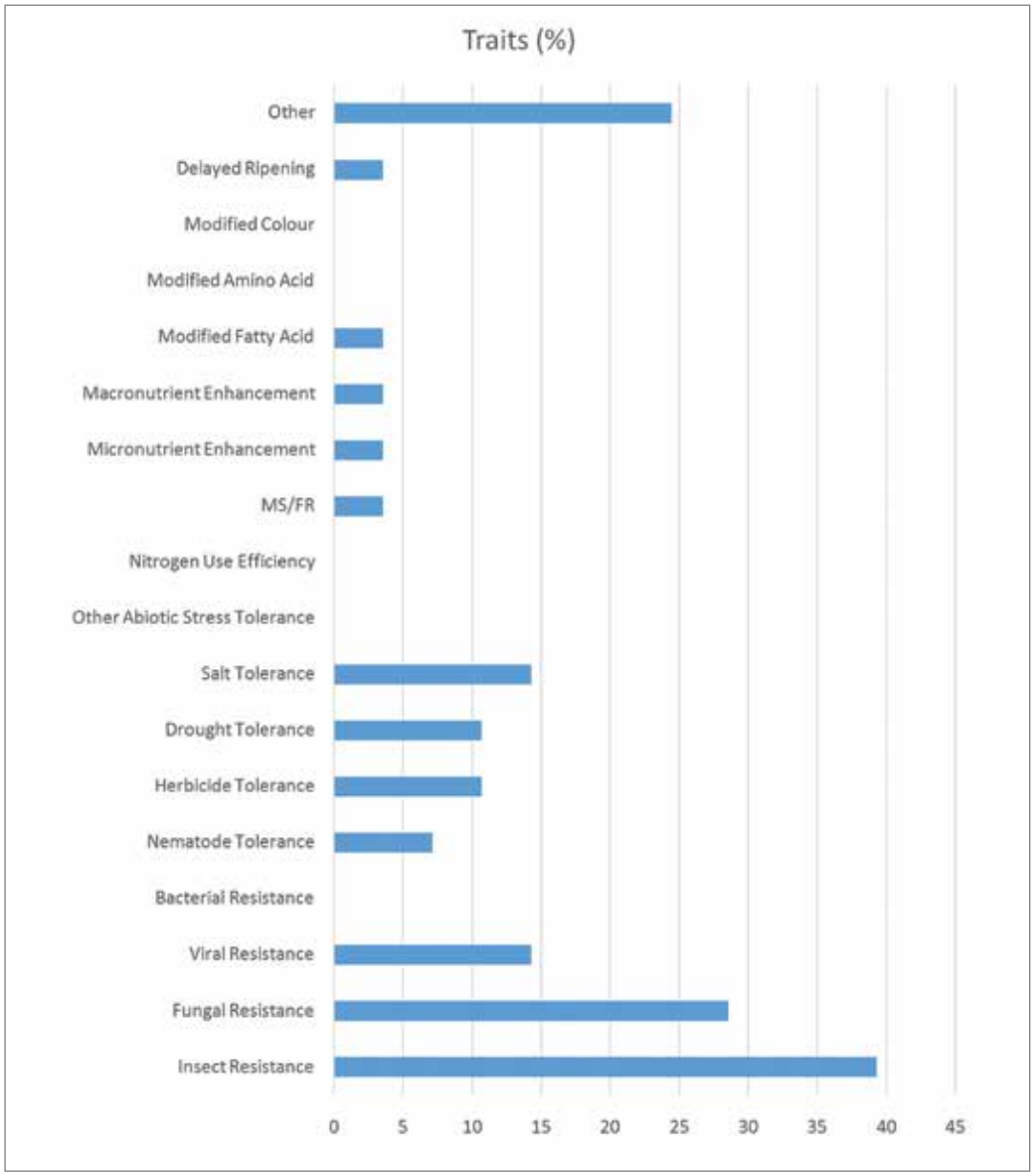
Iran

Q40. If no, do you expect it to be approved in India first? (35/208)

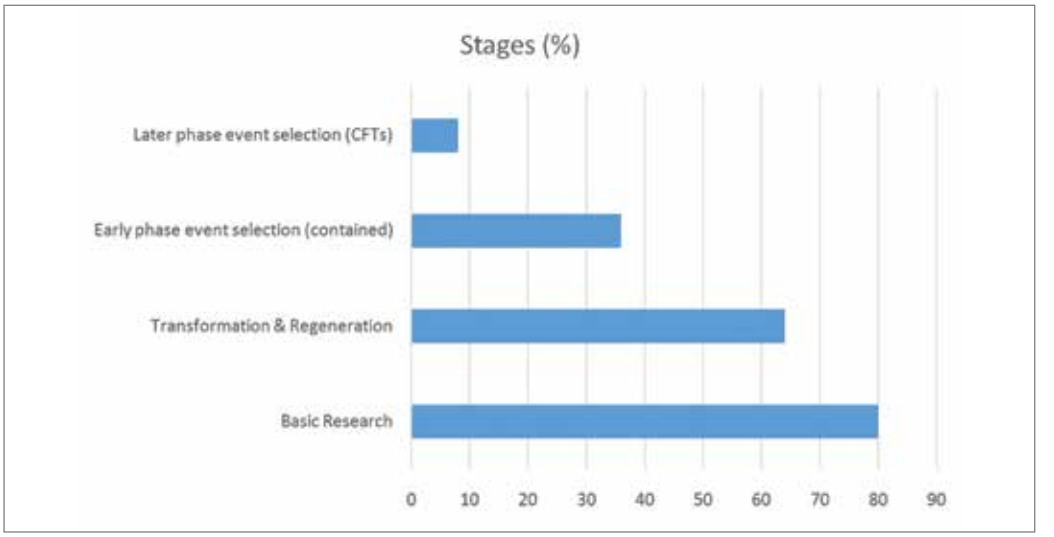


CROP SPECIES 5

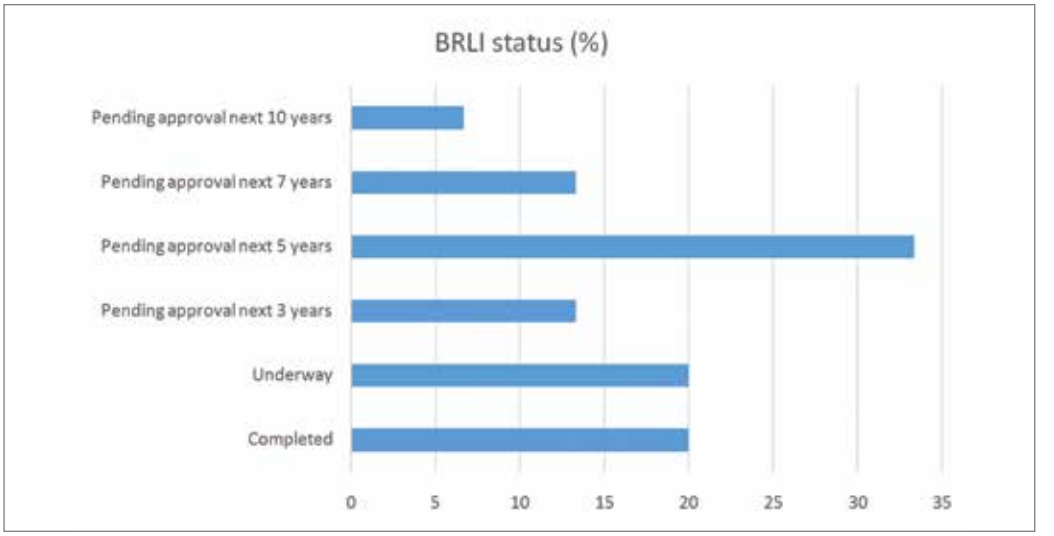
Q41. Please indicate which trait or traits are being studied (select as many as apply): (28/215)



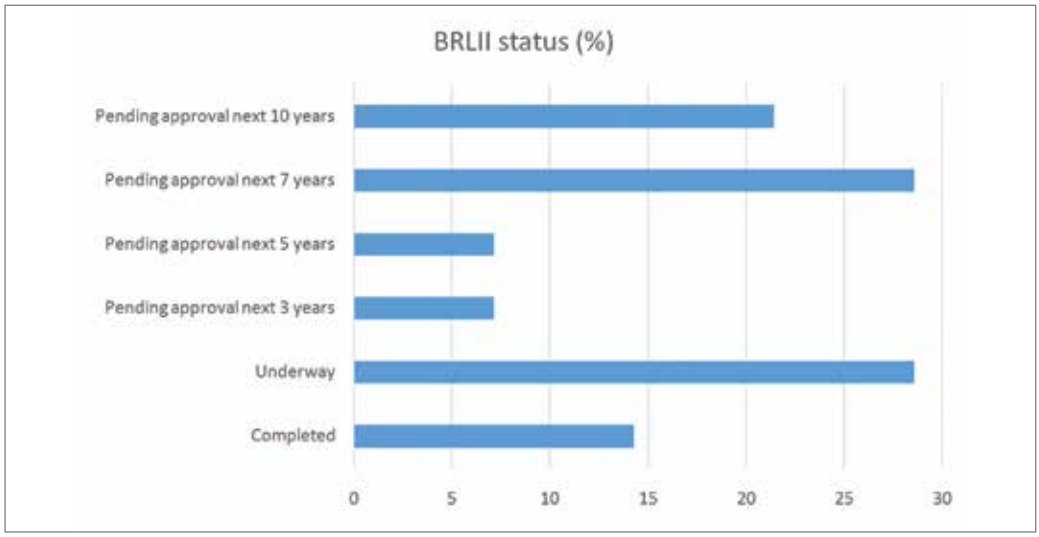
Q42. Which stage(s) of product development have been completed to date? (25/218)



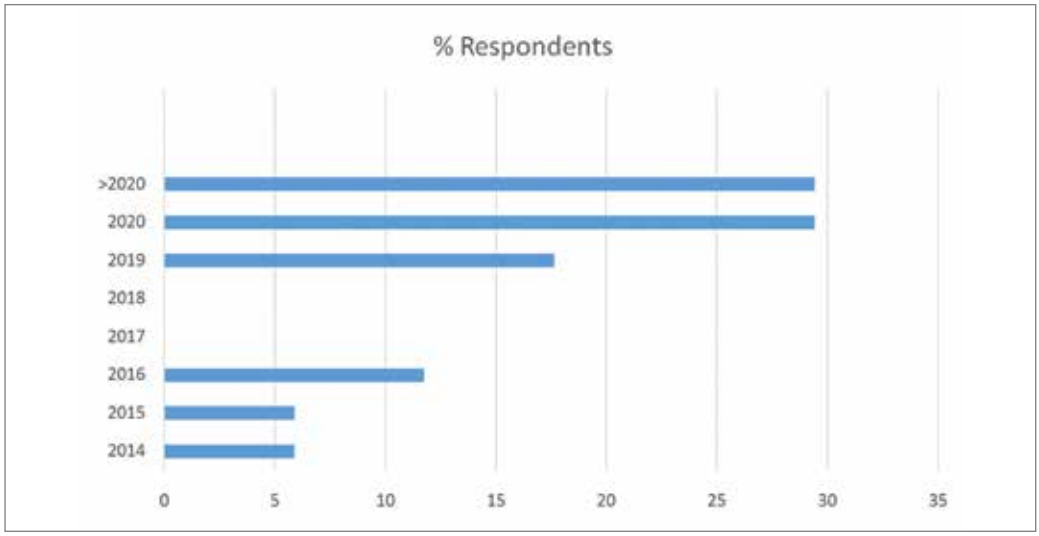
Q43. Which stage of BRLI trials have been completed to date? (15/228)



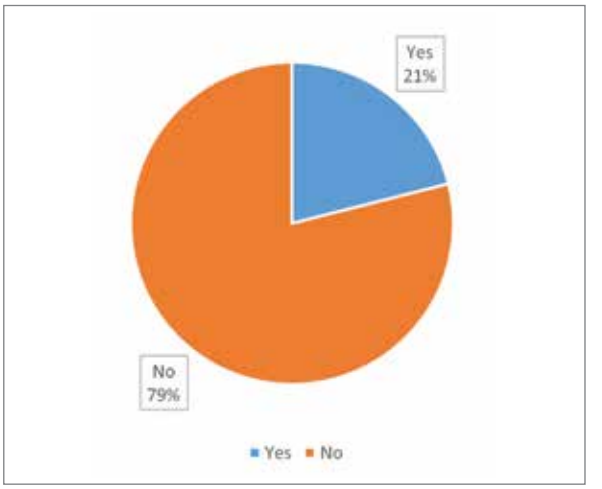
Q44. Which stage of BRLII trials have been completed to date? (14/229)



Q45. When do you anticipate submitting this product for commercial approval? (17/226)



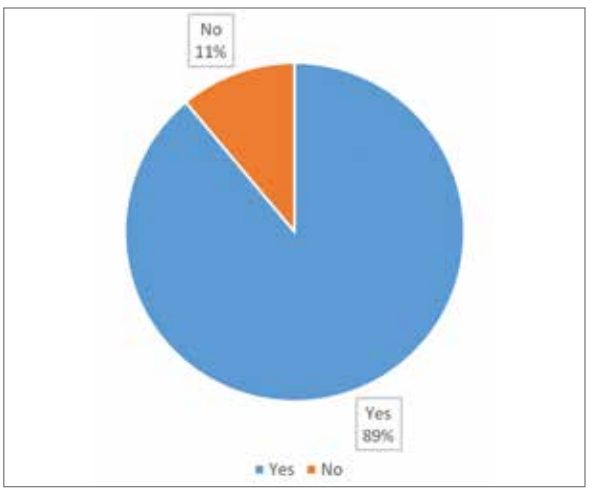
Q46. Has this product been approved in any other countries? (19/224)



Q47. If yes, please indicate which countries. (3/240)

Canada	USA	

Q48. If no, do you expect it to be approved in India first? (18/225)



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