

Comments on the European Union Food Safety Authority's Pest Risk Assessment for *Phyllosticta citricarpa*

CBS Expert Panel

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Summary

The European Food Safety Authority (EFSA) provided a draft Pest Risk Assessment (PRA) on *Phyllosticta citricarpa*, causal agent of citrus black spot (CBS) for public comment in 2013 and EFSA released its final PRA in 2014. An international panel of scientists with CBS expertise (CBS Expert Panel, referred to herein as the Expert Panel) studied EFSA's draft PRA and provided substantive comments to EFSA during the consultation process in a detailed 55-page document (available at <http://www.citrusres.com/market-access>). The Expert Panel also studied the final EFSA PRA and EFSA's responses to the comments it received during the public consultation process. The Expert Panel considers the EFSA responses to be deficient and the conclusions of the final EFSA PRA to be erroneous and in conflict with the body of scientific evidence that is currently available. The Expert Panel holds the view that EFSA has not provided new reliable scientific evidence to support EFSA's conclusions. The Expert Panel maintains the view that in accordance with other PRAs, the EU is not at risk of establishment and spread of *P. citricarpa* via the fresh citrus fruit pathway.

Background

Phyllosticta citricarpa (Mc Alpine) Van der Aa is a fungal pathogen that causes Citrus Black Spot (CBS) disease on *Citrus* spp. (Kotzé, 1981; Kotzé 2000). *Phyllosticta citricarpa* occurs in several countries where citrus is grown, but has not been recorded to occur in European Union Member States (EPPO, 2014). South African scientists conducted a *P. citricarpa* PRA in 2000, which was further expanded through several bilateral exchanges between South African and EU CBS working groups over the period 2001 to 2009 (South African CBS PRA, 2001-2009). The United States Department of Agriculture (Animal and Plant Health Inspection Service, Plant Protection and Quarantine) also conducted a citrus fruit pathway *P. citricarpa* PRA (USDA-APHIS, 2010). These two assessments similarly concluded that the fresh citrus fruit pathway does not represent an epidemiologically significant pathway for the entry, establishment and spread of *P. citricarpa*.

On 31 July 2013 EFSA released a draft *P. citricarpa* PRA (EFSA, 2013) and invited public comment. Since the draft EFSA PRA was in conflict with the conclusions of previous *P. citricarpa* PRAs, an international panel of scientists was convened to provide a detailed scientific evaluation of the draft EFSA PRA. The Expert Panel's comments (CBS Expert Panel, 2013) were provided to EFSA prior to closure of the public comment period on 12 September 2013. On 21 February 2014, EFSA released its final *P. citricarpa* PRA (EFSA, 2014a) as well as a document with its responses to the comments provided through the public consultation process (EFSA, 2014b). The Expert Panel studied EFSA's final *P. citricarpa* PRA and EFSA's responses to the comments it received. This document provides a summary of the Expert Panel's comments on these EFSA documents.

EFSA's responses to comments provided on the draft PRA

The Expert Panel considers EFSA's responses to the comments provided on the fresh fruit pathway and climate suitability for *P. citricarpa* establishment in EU of questionable scientific merit, as reflected in the following.

1. Many of EFSA's responses to the comments received do not address the technical and scientific essence of the inputs provided. In some cases, EFSA states that it has considered the comments, but there is no indication that it has indeed done so, or has changed the EFSA position based on the input and in some cases EFSA's responses simply do not relate directly to the comment provided. For example, EFSA response numbers: 3, 4, 5, 7, 21, 23, 25, 29, 37, 40, 41, 42, 64, 67, 69, 82, 92, 94, 106,

110, 123, 125, 130, 135, 137, 140, 154, 156, 164, 168, 178, 181, 186, 210, 216, 230, 232, 235, 256, 262, 263, 273, 292, 293, 294, 317, 324, 327, 333, 335, 336, 338, 380.

2. In some cases EFSA's responses to the comments provided suggest that EFSA purports to have a better understanding of the research results than the researchers who themselves conducted the research. EFSA seems to have overlooked the fact that, in many cases, the authors of the scientific papers were members of the Expert Panel. In other words, EFSA has attached more scientific value to its own interpretation of the published results than the interpretation of the authors themselves. For example EFSA response numbers: 24, 35, 61, 64, 66, 68, 72, 93, 135, 223, 234, 235, 236, 238, 252, 254, 257, 259, 264, 272, 273 & 336; and in particular EFSA's response numbers 135 and 223.

3. Some of the EFSA responses seem to be based on the premise that EFSA has a better understanding of CBS than the Expert Panel members. This is particularly problematic when it relates to local conditions where CBS occurs, or to familiarity with CBS under relevant field conditions. For example EFSA response numbers: 3, 23, 24, 31, 32, 61, 62, 64, 66, 68, 72, 74, 93, 112, 119, 125, 130, 135, 139, 140, 150, 151, 216, 223, 234, 235, 236, 237, 238, 247, 250, 252, 254, 258, 260, 264, 268, 269, 270, 271, 272, 273, 274, 295, 328, 329 & 331. Of particular concern is EFSA's disregard of scientific evidence (and Expert Panel's comments) indicating the known duration of fruit susceptibility (61, 67, 234, 327) and the relatively high lower-temperature threshold for *P. citricarpa* spore release and infection (62, 236), as well as EFSA's interpretation of the probability of transfer, infection and establishment (125, 130, 135, 139, 140, 151, 268, 271, 272). In response to their relative CBS inexperience, EFSA responded (247) that it has benefitted from the technical input from the Expert Panel, but then illogically disregarded most of the Expert Panel's inputs and came to conclusions that are the opposite of the Expert Panel's.

4. In some cases, EFSA's responses provide a scientifically weak argument (that is without appropriate evidence, unpublished work, untested assumptions, inappropriate test conditions, untested hypothetical reasoning or based on erroneous information) as justification for disregarding comments that have strong scientific or evidential support. For example EFSA response numbers: 19, 20, 21, 24, 32, 61, 62, 64, 66, 69, 72, 74, 83, 94, 99, 104, 128, 130, 135, 139, 140, 150, 151, 174, 175, 177, 216, 217, 223, 232, 234, 236, 237, 252, 254, 257, 258, 259, 261, 262, 263, 267, 269, 273, 275, 276, 316, 317 & 333. Of particular concern, is EFSA's assessment of climate suitability for *P. citricarpa* establishment and the

pest categorization of *P. citricarpa* in the EU (83, 84), the probability of transfer, splash dispersal (125, 130, 135, 139, 140, 151) and probability of entry (230).

5. In contrast with point 4 above, EFSA in some cases enthusiastically supports comments that were without substantiation, supportive evidence or relevance, but were apparently in agreement with a position taken by EFSA. For example, EFSA response numbers 63, 133, 137, 183, 184, 185 & 255.

6. Some of EFSA's responses reflect a lack of impartial objectivity. This is reflected by a qualitative and simplistic categorization of the relationship between comments provided and EFSA's response. Comments supportive of a position in the draft EFSA *P. citricarpa* PRA were either accepted on face value or were given serious consideration. Other comments (including those of the Expert Panel) that did not support EFSA's position were either ignored or were given cursory consideration without affecting any amendment to the final EFSA assessment. This suggests a systemic failure of EFSA PRA process in that EFSA seems to have been biased towards defending an existing position rather than conducting an unbiased, objective assessment of the available peer reviewed scientific evidence pertaining to the risk potential.

7. The suggestion that EFSA's assessment was biased toward defending an existing position, is also supported by the observation that EFSA has generally over-stated various risk ratings, which, in spite of scientific literature to the contrary, EFSA attempted to justify by the adoption of highly subjective uncertainty levels. This was pointed out by the Expert Panel (particularly in 273, 292, 294, 295, 337, 339, 359), but in the final PRA the risk ratings remained unchanged.

The CBS Expert Panel's opinion on the conclusions of the EFSA PRA

While the Expert Panel agrees with the final conclusion of the Tahiti lime fruit pathway (no risk), the Expert Panel strongly disagrees with the final EFSA PRA in general and with specific conclusions of the PRA, as is reflected in the following.

1. The Expert Panel provided detailed information indicating the erroneous nature of specific and overall conclusions contained in the draft EFSA *P. citricarpa* PRA. The risk ratings and conclusions in the final EFSA PRA were not amended in response to those comments and EFSA did not provide scientifically sound justification for not appropriately adjusting the key conclusions in the final EFSA PRA.

2. EFSA has used weak evidence, such as unpublished, non-peer reviewed findings from experiments conducted under artificial conditions, lacking in appropriate scientific procedure, replication and controls, to support key positions that are in conflict with scientifically sound published evidence and the Expert Panel's comments. An example is EFSA's use of the Perryman and West (2014) report, which used contrived laboratory conditions with peculiar, large, artificial lesions, to support its peculiar views on splash dispersal. These views are in conflict with the Expert Panel's experience and other available scientific information. Another example is EFSA's refusal to include positive and negative controls in their climate modeling (263, 273). The inclusion of such controls is a standard scientific principle and the Expert Panel regrets EFSA's refusal to include these controls as it would have placed their findings in context and alignment with reality. In fact, evidence of significant differences in model predictions for EU localities and positive and negative control localities was presented to EFSA, and also published by EFSA (2008) (see comment 264, 272), but this was not regarded by EFSA (2014a). A further example is that EFSA generated highly uncertain leaf wetness simulation data (as acknowledged by EFSA in 2008) that have not been subjected to peer review through publication, and used these data as an important component of the climate modeling work conducted by EFSA in the final PRA.

3. EFSA continued to exaggerate the risk ratings by reflecting what they considered to be possible scenarios as having a "likely" risk rating. Moreover, EFSA continued failing to appropriately consider the cumulative reduction in probability arising from the combination of unlikely sequential events that all have to occur to produce an outcome of epidemiological significance. For example, EFSA considered some aspects of the latter in its simplified pathway model, which indicated that if fresh fruit were to be imported under no regulation from medium to high CBS origins, some contaminated fruit or fruit waste might end up in waste piles in "close" proximity to citrus orchards. EFSA acknowledged that "the pest still has some limitations for transfer to a suitable host in the risk assessment area", but still concluded that "the pathway should be assessed as moderately likely". This assessment of risk ignores the scientific evidence and comments provided by the Expert Panel, which indicated the debilitating nature of the so-called limitations in terms of CBS epidemiology.

4. EFSA cannot claim that its final *P. citricarpa* PRA has been subjected to thorough and rigorous public comment. Key components rely heavily on unpublished, non-peer reviewed, EFSA-commissioned evidence, that was not made available at the time that the draft report was released for comment.

5. The Expert Panel considers EFSA's responses to many comments that the Expert Panel provided and that pertain to key components of the final EFSA *P. citricarpa* PRA to be deficient.

6. The Expert Panel considers aspects of the unpublished data provided by EFSA in support of key components of EFSA's assessment to be unreliable, erroneous and in conflict with strong scientific evidence. An example is the EFSA approach to climate modelling and its disregard of the comments provided by the Expert Panel, some of its members whom EFSA quotes in support of their own contested approach.

7. EFSA maintains conclusions in its final PRA that are in conflict with the body of available scientific evidence and expert opinion, without having provided reliable evidence to support such alternate views.

8. In the absence of reliable evidence to the contrary, the Expert Panel upholds the assessment it communicated to EFSA in 2013, namely: "we do not agree with the EFSA (2013)'s assessment of risk and we consider suitable expert opinion and scientific information to weigh strongly in favour of the no-risk assessment".

9. In relation to the final EFSA *P. citricarpa* PRA, the Expert Panel accordingly upholds the following conclusion, which it reached when considering the draft EFSA *P. citricarpa* PRA: "In conclusion, we are in agreement with earlier PRAs, conducted by South Africa and USA, in which it was concluded that citrus fruit is not an epidemiologically significant pathway for *P. citricarpa* to enter, establish, spread and have significant economic impact within the PRA area (EU)".

Conclusion

The Expert Panel considers the final EFSA *P. citricarpa* PRA to be deficient in its assessment of scientific evidence pertaining to the risk of entry, establishment and spread of *P. citricarpa* in association with the fresh citrus fruit pathway. The Expert Panel finds EFSA's handling of the scientific and other comments provided on the draft EFSA *P. citricarpa* PRA to be lacking in due care and scientific objectivity. The manner in which EFSA considered public comment suggests a systemic failure of the EFSA PRA process in that EFSA seems to have been biased towards defending an existing position rather than conducting an unbiased, objective assessment of the available scientific evidence pertaining to the risk potential.

The Expert Panel strongly disagrees with the majority of the EFSA *P. citricarpa* PRA conclusions and does not consider the PRA to provide credible scientific evidence that supports EFSA's conclusions. The Expert Panel does not consider the EFSA *P. citricarpa* PRA to have presented scientific evidence that supports a change in the Expert Panel's conclusions as reflected in the comments it provided to EFSA in 2013 (CBS Expert Panel, 2013). The Expert Panel maintains that consideration of the body of available scientific evidence and familiarity with the CBS disease supports the conclusions of earlier *P. citricarpa* PRAs (South African CBS PRA, 2001-2009; USDA-APHIS, 2010) that fresh citrus fruit does not pose risk as a potential pathway for the entry, establishment and spread of *P. citricarpa* in the European Union.

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