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Section 18 Quarantine Exemption Request
For The Addition of
Tebuconazole + Pyraclostrobin (Headline SBR, Headline STAR)

to the 2003 submission for Propiconazole (Tilt, PropiMax, Bumper), Tebuconazole, (Folicur), Myclobutanil (Laredo EC, Laredo EW), Propiconazole + Trifloxystrobin (Stratego), Tetraconazole (Domark), Pyraclostrobin (Headline), Pyraclostrobin + Boscalid (Pristine), And Azoxystrobin + Propiconazole (Quilt)

Fungicides On Soybean For Control Of
Australasian Soybean Rust (*Phakopsora pachyrhizi*)

Submitted by the
Minnesota Department of Agriculture
South Dakota Department of Agriculture

Contact Person and Qualified Expert (166.20(a)(1))

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See also list of members of Technical Science Working Group on Soybean Rust (**Appendix A**)

DESCRIPTION OF PESTICIDE REQUESTED (166.20 (a) (2))

Pesticides requested: Several products have emerged as potentially efficacious against Australasian soybean rust in international trials. No registrant has indicated the ability to meet the needs of the soybean industry should an Australasian soybean rust epidemic occur in the US in 2005. As such, we request that several products be considered for approval. Biological and economic considerations will be presented to support the use of additional products beyond those already labeled.

The products requested Headline SBR/Headline STAR, are a co-pack mixture or premix, respectively, of tebuconazole and pyraclostrobin. Both of these products have received prior approval from EPA for use against soybean rust in soybeans. Pyraclostrobin (Headline) has a Section 3 label for this purpose and tebuconazole (Folicur) has been approved under the master submission of this Section 18. Headline SBR/Headline STAR was not included in the Section 18 submission because it contains active ingredients from two registrants and the contractual arrangements were not finalized until recently. In South Dakota and Minnesota, the active ingredients in Headline SBR/Headline STAR are widely used in wheat and as such are likely to be familiar to producers and could likely become broadly accepted. Additionally, it is expected that this product will provide excellent control of soybean rust in the region.

Limited efficacy data is currently available for any product against soybean rust. Pending the outcome of continuing comparative fungicide efficacy trials being conducted in Africa and South America under USDA, ARS direction, the following products are listed as candidates. While each state may make its own product decisions, depending on local conditions, it is suggested that several rather than one or two fungicides should be requested. This is considered important from several perspectives (biological and economic justifications).

Due to the large acreage potentially impacted, registrants have informed the states that no single product will be available in sufficient quantity to treat the potential land area impacted by soybean rust. See letters of support **(Appendix B – i through B – vi)**.

This amendment adds a co-pack product of tebuconazole and pyraclostrobin (Headline SBR) and a premix of the same active ingredients (Headline STAR) to the original submission. The Headline SBR formulation is intended as a stopgap formulation to get the proper rate combinations of the combined active ingredients into the hands of producers. As the formulation and packaging of the premix product is finalized, it will replace Headline SBR in this market. These active ingredients have either already received full Section 3 labeling (pyraclostrobin) or have been approved for conditional use on the initial submission of this Section 18 (tebuconazole).

A revised Section 18 petition may be submitted at a later date as more current data becomes available or as need for more products becomes apparent due to short product supplies and severe disease or disease potential.

Because of the product availability and dual mode of action, Headline SBR/Headline STAR would be positioned with Quilt and Stratego and ahead of solo strobilurin products for preference in use. This product functionally replaces Pristine in the marketplace, providing a mechanism for strobilurin resistance management with greater efficacy than is available from the boscalid component of Pristine.

Common Chemical Name (Active Ingredient): tebuconazole + pyraclostrobin
Trade Names(s)And EPA Reg. No.: Headline® SBR, EPA Reg. Number xxx-xxxx
Formulation: 3.6SC (tebuconazole) and 2.09EC (pyraclostrobin)
% Active Ingredient: 38.7% (3.6 lb/gal tebuconazole/gal)

23.6% (2.09 lb/gal pyraclostrobin/gal)
Packaged in a co-pack twin container
Manufacturer: BASF Corporation; Research Triangle Park, NC, 27709

Common Chemical Name (Active Ingredient): tebuconazole + pyraclostrobin
Trade Names(s)And EPA Reg. No.: Headline® STAR, EPA Reg. Number xxx-xxxx
Formulation: 2.09EC
% Active Ingredient: 12.7% (1.12 lb/gal tebuconazole/gal) + 11.0% (0.97 lb/gal pyraclostrobin/gal)
Manufacturer: BASF Corporation; Research Triangle Park, NC, 27709

DESCRIPTION OF PROPOSED USE (166.20 (a)(3))

Sites to be Treated: Soybeans

Method of Application: Ground or Aerial

Rate of Application (tebuconazole + pyraclostrobin): 0.089 lb (1.4 oz) tebuconazole + 0.077 lb (1.2 oz) pyraclostrobin a.i./A in 7.8 fl oz Headline SBR or 10.2 fl oz Headline STAR product per acre

Maximum Number of Applications: Maximum of two applications of Section 18 products. In many cases three to four total fungicide applications will be made.

Total Acreage to be Treated: 2 million acres of soybeans in South Dakota (represents ~50% of 4 million soybean acres potentially impacted, primarily in eastern South Dakota). At the current time, only about 15% of the soybean acres are treated with a fungicide, none of which is foliar application. All treated soybean acres in SD are currently treated with seed treatment products.

3.6 million acres of soybeans in Minnesota (represents ~50% of 7.2 million soybean acres potentially impacted, primarily in southern Minnesota).

36.9 million acres of soybeans in the United States (represents ~50% of 73.8 million soybean acres potentially impacted.

Australasian soybean rust models **(Appendix C)** suggest that most of the soybean acres in the United States could be compromised by soybean rust at the point that the disease becomes established in the country. Unfortunately, at the current level of knowledge of this disease, there is no way of knowing with any degree of scientific certainty, what the risk of this disease will be in any specific location in advance of the epidemic. States where the epidemic originates may have a much higher percentage of their acreage impacted by the disease or treated to prevent infection.

In another scenario, the pathogen could be accidentally or purposely introduced into the Midwestern soybean production belt. In that scenario, the epidemiological dynamics of the pathogen's spread may be very different, depending on the site of the initial introduction. In accordance with the 2002 Agricultural Bioterrorism Protection Act, *Phakopsora pachyrhizi* has been identified as a biological agent with potential to pose a severe threat to plant health or plant products (Federal Register December 13, 2002 – 67:76908-76938 - http://www.aphis.usda.gov/vs/ncie/pdf/btarule.pdf) **(Appendix D)**.

From November 10 to December 1, 2004, Phakopsora pachyrhizi was identified in nine southeastern states in the US. While it is unknown if the organism will overwinter in the US, this occurrence has shown that the pest will survive and cause disease in the US environment. As such, producers are prepared to treat with fungicides in 2005, should the disease recur. In SD and MN, treatment recommendations will be based on monitoring for the disease in our states as well as reports of the disease elsewhere in the US.

Total Amount of Pesticide to be Used: Assuming 2 million acres of soybeans in South Dakota and 3.6 million acres in Minnesota, the following scenario applies: (assumes that only one of the products used over the treated acreage – actual use may reflect a combination of products).

South Dakota
121,875 gal. of Headline® SBR co-pack product/Headline® STAR premix product or 332,000 lb a.i. (178,000 lb tebuconazole + 154,000 lb pyraclostrobin) for one application to 2 million acres.

Minnesota
219,375 gal. of Headline® SBR co-pack product/Headline® STAR premix product or 597,600 lb a.i. (320,400 lb tebuconazole + 277,200 lb pyraclostrobin) for one application to 3.6 million acres.

Tebuconazole + pyraclostrobin co-pack (Headline® SBR) is a pre-packed combination of two systemic products, a mobile triazole fungicide (tebuconazole) that can be used as preventative/systemic eradicant and a preventative/protectant strobilurin (pyraclostrobin) with only modest movement from the site of application. Combination products composed of QoI, strobilurin and others (FRAC Group 11) mode of action fungicides, with SBI mode of action fungicides, triazole and others (FRAC Group 3) have proven to be the most efficacious products used in South America. While tebuconazole has post-infection activity that can stop pathogen establishment in the early phases of disease development and anti-sporulant activity, reducing inoculum production, this product premix should not be used as a late curative treatment. **This exemption request is for the use of one or two applications of tebuconazole + pyraclostrobin (Headline® SBR) for control of Australasian soybean rust.** This disease organism is expected to attack the crop after canopy development and response to fungicides have required multiple applications for optimum disease management in other parts of the world. **Use of tebuconazole + pyraclostrobin on soybean would result in only 0.17 million lbs a.i. Headline® SBR/Headline® STAR(89,000 lb ai tebuconazole + 77,000 lb ai pyraclostrobin applied only once and 178,000 lb ai tebuconazole + 154,000 lb ai pyraclostrobin if applied twice) used if 1 million soybean acres were treated.**

Headline® STAR is a similar product with the same active ingredients at the same ratio. At the point this product is ready for the market it will supercede Headline® SBR. This formulation of pyraclostrobin with a co-fungicide is intended as a functional replacement for Pristine (pyraclostrobin + boscalid), pairing the pyraclostrobin with a much more efficacious partner in tebuconazole than the boscalid in Pristine with its limited activity against *Phakopsora pachyrhizae*.

Under this exemption, the listed products could be used for **one or two applications** in a given season. In combination with products that are already registered, control should be achieved where the following guidelines are followed:

Stage of Crop Growth When Treatment Will Be Made: R-1 to R-6 (beginning flowering to full seed).

Use Season: Immediately upon the introduction of Australasian soybean rust into the United States until September 15 of the final production year approved in this action.

Additional Restrictions, User Precautions & Requirements of Applicators: Apply products in a sufficient volume of water to ensure adequate coverage, consistent with product labeling, as follows:

Application Volume Recommendations for Soybean Rust Sec. 18 Fungicides

Product		Volume (gal)	
Active Ingredient (ai)	**Trade Name**	**Ground**	**Air**
tebuconazole + pyraclostrobin	(Headline® SBR co-pack Headline® STAR premix)	10-20	5-10

Pursuant to South Dakota state law, all applicators applying these products must be certified.

ALTERNATIVE METHODS OF CONTROL (166.20(a)(4))

See master submission

Large economic losses due to Australasian soybean rust loom if the disease is allowed to progress unchecked. Losses in Brazil in 2002 exceeded 60% in some fields **(Appendix F)**. Under conditions of severe disease pressure, soybean producers need systemic products that are in good supply. Use of any fungicide product on soybeans has been very limited, because of lack of availability of suitable efficacious registered products to address real disease needs and infrequency of severe disease, and lack of serious disease that would be effectively controlled by fungicides.

Recent data generated in Brazil, indicates that triazole fungicides are quite effective against this pathogen. Triazole fungicides, have proven most consistent in providing curative control with the minimum acceptable risk of fungicide resistance and with superior economics to registered products **(see efficacy and economics sections).** As a means of comparison, a one million acre figure will be used to consider use rates of each of the products requested. Use in specific states can be easily calculated from that figure.

(modified from initial submission)

Suggested product use regimen *(revised based on greater South American experience):*

- **If disease is expected, but not yet present (preventative):**

  LOW RISK – PRIOR TO DETECTION:
  Crop no earlier than beginning flowering (R1)* and no later than full seed (R6); based on reliable reports, the potential for soybean rust in your area is low risk and it has NOT been detected in nearby areas.

  - NO APPPLICATION – CONTINUE SCOUTING

- **If disease is expected, but not yet present (preventative):**

  HIGH RISK – PRIOR TO DETECTION: PREVENTATIVE TREATMENT
  Crop no earlier than beginning flowering (R1)* and no later than full seed (R6); based on reliable reports, the potential for soybean rust in your area is high risk, but it has NOT been detected locally.

  - Initial Treatment
    - Treat with ***chlorothalonil****; **-OR-**
    - ***strobilurin*** such as azoxystrobin (Quadris) or pyraclostrobin (Headline); **-OR-**
    - ***triazole*** such as propiconazole, tebuconazole, myclobutanil, or tetraconazole; **-OR-**
    - ***premix*** such as propiconazole + trifloxystrobin (Stratego), propiconazole + azoxystrobin (Quilt), or tebuconazole + pyraclostrobin (Headline SBR, Headline STAR).
  - If a second application is needed,

- Treat with a ***triazole*** (propiconazole, tebuconazole, myclobutanil, or tetraconazole), **-OR-** a
- ***premix*** such as propiconazole + trifloxystrobin (Stratego), propiconazole + azoxystrobin (Quilt), or pyraclostrobin + boscalid (Pristine), **or** tebuconazole + pyraclostrobin (Headline SBR, Headline STAR).

♦ If a third application is needed,
- treat with a ***premix*** such as propiconazole + trifloxystrobin (Stratego), propiconazole + azoxystrobin (Quilt), or tebuconazole + pyraclostrobin (Headline SBR, Headline STAR), **-OR-**
- a ***triazole*** (propiconazole, tebuconazole, myclobutanil, or tetraconazole) *if no other triazole has been applied.*

♦ CONTINUE SCOUTING

➢ **If disease is established on site (curative treatment):**

EARLY ESTABLISHMENT - CURATIVE TREATMENT

Crop no earlier than beginning flowering (R1)* and no later than full seed (R6); soybean rust is present at barely detectable levels in the lower to mid canopy in your fields or your neighbor's fields *(note: soybean rust will not respond to fungicides once the disease is well-established in a field)*:

♦ Initial Treatment
- Treat with ***premix*** such as propiconazole + trifloxystrobin (Stratego), propiconazole + azoxystrobin (Quilt), or tebuconazole + pyraclostrobin (Headline SBR, Headline STAR) – **OR -**
- a ***triazole*** (propiconazole, tebuconazole, myclobutanil, or tetraconazole).

♦ If a second application is needed,
- Treat with a ***premix*** such as propiconazole + trifloxystrobin (Stratego), propiconazole + azoxystrobin (Quilt), or tebuconazole + pyraclostrobin (Headline SBR, Headline STAR) or a triazole (propiconazole, tebuconazole, myclobutanil, or tetraconazole, **- OR -**
- a ***triazole*** (propiconazole, tebuconazole, myclobutanil, or tetraconazole), **- OR –**

♦ If a third application is needed,
- Treat with a ***premix*** such as propiconazole + trifloxystrobin (Stratego), propiconazole + azoxystrobin (Quilt), or tebuconazole + pyraclostrobin (Headline SBR, Headline STAR) *if no more than one previous premix application has been made* **– OR –**
- a ***triazole*** (propiconazole, tebuconazole, myclobutanil, or tetraconazole, ***-OR-***

♦ CONTINUE SCOUTING

➢ **If disease is established on site (curative treatment):**

DISEASE ESTABLISHED – INCIDENCE (% of plants with any amount of disease) EXCEEDS 10% IN THE MID CANOPY:

Crop no earlier than beginning flowering (R1)* and no later than beginning seed (R6); based on reliable reports, soybean rust is present in your field and severity is high.

♦ NO APPLICATION RECOMMENDED FOR DISEASE CONTROL IN THIS FIELD – FUNGICIDES NOT EXPECTED TO PROVIDE ACCEPTABLE CONTROL OR ECONOMIC RESPONSE‡

*** Do not apply chlorothalonil if any active pustules are evident**

† Do not apply strobilurins solo in a curative mode or as a second application if a strobilurin was used for the first application.

‡ Fungicides applied after disease incidence exceeds 10% in the mid canopy generally do not produce a satisfactory response.

Data from some parts of the world suggest that fungicide applications made during the vegetative stages are sometimes beneficial. Most data, however, suggest that maximum benefit when using fungicides to manage soybean rust is achieved when sprays are applied between beginning flowering (R1) through full pod (R6).

A single fungicide application may be adequate for economical disease control if initial disease outbreak occurs late in the season, or where disease development is significantly slowed by an unfavorable environment. **Experience in South America suggests that a third application may be a rare occurrence**.

EFFICACY OF USE PROPOSED UNDER SECTION 18 (166.20(a)(5))

See master submission for efficacy of the two active ingredients individually. These two components have consistently performed among the most efficacious products in their respective chemistries. Data is limited for the co-pack (Headline SBR) and premix (Headline STAR), but three independent trials from Brazil are presented below. In one study (Fig 1) the mixture of tebuconazole +pyraclostrobin provided significantly better disease control and yield than either component individually, However the combination was only numerically better than the low rate of pyraclostrobin alone. Similarly, the combination provided significantly higher yield than tebuconazole or the low rate of pyraclostrobin alone. Similar performance was observed against Cercospora and Septoria, showing the broad spectrum disease protection possible with this mixture (Fig 2).

Table 1. Efficacy of tebuconazole + pyraclostrobin mixture on Asian soybean rust (cooperator: D. Gleba, UFSM; cultivar CD205 planted January 30, 2004; fungicides applied March 26 at R1 and April 11, 2004 at R4).

Treatment	Rate (g ai/ha)	Rate (lb ai/acre)	Rust Severity AUDPC*	Yield (kg/ha)
untreated	--	--	982 g	1644 a
pyraclostrobin	112	0.1	153 de	1823 abc
pyraclostrobin	168	0.15	165 e	1960 bcde
pyraclostrobin + tebuconazole	84+84	0.075+0.075	127 bcd	2158 e
tebuconazole	112	0.1	170 e	1863 abcd

*AUDPC = area under the disease progress curve

Table 2. Efficacy of tebuconazole + pyraclostrobin mixture on late season diseases (cooperator: D. Gleba, UFSM; cultivar RS10 planted Dec 3, 2003; fungicides applied Feb 7 at R2 and Feb 20, 2004 at R5.1).

Treatment	Rate (g ai/ha)	Rate (lb ai/acre)	Cercospora & Septoria Disease (%)	Yield (kg/ha)
untreated	--	--	16.2 f	1890 a
pyraclostrobin	112	0.1	1.8 a	2253 bc
pyraclostrobin	168	0.15	2.1 ab	2377 bc
pyraclostrobin + tebuconazole	84+84	0.075+0.075	3.0 cd	2364 bc
tebuconazole	112	0.1	3.4 cd	2086 abc

Under curative conditions, where the fungicide treatments were applied at the onset of soybean rust (Fig 3), the mixture and combination provided comparable control in each third of the soybean canopy.

Table 3. Curative control of tebuconazole + pyraclostrobin mixture on Asian soybean rust (cooperator: TAGRO, Rio Verde; cultivar BRSGO Jatai planted Dec 1, 2003; fungicides applied Feb 4 at 1% rust severity in the lower canopy and Feb 21, 2004).

Treatment	Rate (g ai/ha)	Rate (lb ai/acre)	% Rust Severity (R5.1, Mar 1, 2004)		
			Lower Canopy	Middle Canopy	Upper Canopy
untreated	--	--	95.5	67.5	38.7
pyraclostrobin	112	0.1	38.7	19.5	10.2
pyraclostrobin	168	0.15	40.0	19.2	10.0
pyraclostrobin + tebuconazole	84+84	0.075+0.075	9.0	2.5	0.2
tebuconazole	112	0.1	8.0	2.2	0

EXPECTED RESIDUE LEVELS IN FOOD (166.20(a)(6))

See letter of support for details on the following information:

Tebuconazole – Bayer is conducting soybean residue trials in the U.S. in 2003 with the intent of developing data on potential residues of tebuconazole in the various soybean commodities. Tebuconazole residue data is on file with EPA proposing tolerances on bean seed, wheat forage, hay and straw (Federal Register March 19, 2001, 66(53):15437-15443) **(Appendix B – ii of original submission)**.

Pyraclostrobin – The proposed tolerances for pyraclostrobin on soybeans are: soybeans 0.4 ppm, soybean forage 5.0 ppm, soybean hay 7.0 ppm, and soybean aspirated grain fraction 0.25 ppm (MRID 45903602). Existing tolerances for pyraclostrobin have been published in the Federal Register 67:60886-60901, September 27, 2002 **(Appendix B – vi of original submission)**.

DISCUSSION OF RISK INFORMATION (166.20(a)(7))

See letters of support **(Appendix B)** for details on the following information:

Since Headline SBR/Headline STAR contains tebuconazole and pyraclostrobin, risks associated with tebuconazole and pyraclostrobin also apply to Headline SBR/Headline STAR.

See letters of support **(Appendix B – i through B – vi)** for details on the following information:

Tebuconazole – Risk information has previously been submitted and assessed to support the Section 3 registration of tebuconazole on peanuts. A toxicological profile was published in the Federal Register March 19, 2001 **(Appendix B – ii)**.

Pyraclostrobin – Risk information has previously been submitted and assessed to support the Section 3 registration of pyraclostrobin on numerous crops including dry beans, peanuts, sugar beets, wheat, barley, rye, citrus, berries, bulb vegetables, cherry, cucurbit vegetables, fruiting vegetables, root vegetables and strawberries.

Tebuconazole, like propiconazole, tetraconazole, and myclobutanil are triazole fungicides. EPA is evaluating the toxicological significance of triazole metabolites 1,2,4-triazole, triazolylalanine (TA) and triazolylacetic acid (TAA). Of the three metabolites, only 1,2,4-triazole can be considered toxicologically significant and EPA has identified developmental toxicity as the endpoint of concern. An industry Triazole Task Force has submitted worst-case studies **(Appendix J)** to EPA demonstrating a reasonable certainty of no harm for 1,2,4-triazole stemming from triazole-derivative fungicides for food only, as well as for food and water.

COORDINATION WITH OTHER AFFECTED FEDERAL, STATE, AND LOCAL AGENCIES (166.20(a)(8))

The South Dakota Department of Agriculture has provided a copy of this request to the State office of the United States Fish & Wildlife Service; the South Dakota Department of Game, Fish & Parks, Division of Wildlife; and the United States Environmental Protection Agency Region VIII Pesticide Program. Any comments provided to the Department of Agriculture will be forwarded to the EPA as they are received. Enclosed is the federal list of endangered and threatened species known to occur in South Dakota and Minnesota **(Appendix K)**.

Headline SBR/Headline STAR fungicide is a combination of tebuconazole and pyraclostrobin.

Minnesota has 13 listings of threatened and endangered species; nine animals and four plants.

Animals

Of the nine animals, two are mammals (Canada Lynx, Gray Wolf), one is an insect (Karner Blue Butterfly), and three are birds (Bald Eagle, Piping Plover, two different watersheds). The New York State Department of Environmental Conservation registration document http://pmep.cce.cornell.edu/profiles/fung-nemat/tcmtb-ziram/tebuconazole/new-act-ing-tebuconazole.html states that tebuconazole is not toxic to mammals, birds, aquatic invertebrates or aquatic plants when used at the single rate of 0.23 lbs ai/acre. The rate of application in this exemption request is 0.089 lbs ai/acre. Additionally, lynx and wolf are found in mature forests and are not typically found in soybean cultivation areas. Bald Eagles are found in mature forests near rivers, lakes or wetlands, typically not areas of soybean cultivation. The Piping Plover (Great Lakes population and Northern Great Plains population) have habitat of sandy beaches and sandy beaches plus islands respectively. No soybeans are grown in the Piping Plover habitat. The Karner Blue butterfly is found only in Winona county in Minnesota. The Karner Blue butterfly habitat is pine and oak savanna/barrens supporting wild lupine and nectar plants, typically not areas of soybean cultivation. Accordingly, use of tebuconazole under this exemption request would not be a threat to these six threatened and endangered species in Minnesota. The three remaining threatened and endangered animals are the Higgins Eye and Winged Mapleleaf mussels and the Topeka Shiner. In Minnesota, the Higgins Eye and Winged Mapleleaf mussels are found in the St. Croix River between Minnesota and Wisconsin. The counties adjacent to the St. Croix River in Minnesota account for less than one percent of the total soybean acres and are not in the primary soybean production areas of Minnesota. Tebuconazole would not reach the Higgins Eye and Winged Mapleleaf mussel habitat as a result of use under this exemption. Topeka shiners live in small to mid-size prairie streams. Risk of acute exposure of Topeka shiners is mitigated by label language prohibiting application directly to water. To further mitigate risk to Topeka shiners from use of tebuconazole under this sec. 18, the Minnesota sec. 18 Headline SBR/Star use directions would include a statement “To prevent risk to the endangered species Topeka Shiner, Headline SBR/Star should not be applied in Lincoln, Murray, Nobels, Pipestone, or Rock counties if heavy rainfall is imminent.” Based on the above discussion, use of tebuconazole under this exemption request would not be a risk to threatened and endangered fish and aquatic invertebrates in Minnesota.

Pyraclostrobin has minimum toxicity to mammals, birds and insects and is unlikely to pose a direct hazard to threatened and endangered mammals, birds or insects in Minnesota as a result of use under this exemption request. Pyraclostrobin may be toxic to fish and aquatic invertebrates. Risk to threatened and endangered mussels in Minnesota resulting from the use of pyraclostrobin on soybeans under this exemption request would not be expected because the mussel habitat (St. Croix River) is outside the major soybean production areas of Minnesota (see above) and because of label language prohibiting application directly to water. Potential risk to Topeka Shiners from pyraclostrobin as a consequence of its use on soybeans under this exemption is mitigated by label language prohibiting application directly to water and proposed Headline SBR/Star use directions for certain counties if heavy rainfall is imminent (see tebuconazole above). Based on

the above discussion, use of pyraclostrobin under this exemption request would not be a risk to threatened and endangered fish and aquatic invertebrates in Minnesota.

Plants

The four threatened and endangered plant species in Minnesota are the Minnesota Dwarf Trout Lily, the Prairie Bush-Clover, the Western Prairie Fringed Orchid, and Leedy's Roseroot. The Minnesota Dwarf Trout Lily is found on fewer than 600 acres of forest habitat and does not occur in areas of soybean cultivation. The Prairie Bush-Clover is found in prairie habitat. Most of the Prairie Bush-Clover in Minnesota is protected in dedicated state nature preserves, scientific and natural areas and preserves or protected by private landowners through conservation-minded agricultural practices. The Western Prairie Fringed Orchid is found in wet prairies and meadows. Most of the Western Prairie Fringed Orchid in Minnesota is protected in nature preserves and natural areas and by private landowners. Leedy's Roseroot is found on cool, wet groundwater-fed limestone cliffs and is not found in areas of soybean cultivation. Based on the above discussion, use of tebuconazole + pyraclostrobin under this exemption request would not be a risk to threatened and endangered plant species in Minnesota.

NOTIFICATON OF REGISTRANT(166.20(a)(9))

The manufacturers of tebuconazole (Bayer CropScience) and pyraclostrobin (Headline – BASF Corporation) are aware of and supportive of this request**.** Letters of support and draft labels for soybeans have been received **(Appendix B – i through B – vi)**.

ENFORCEMENT PROGRAM (166.20(a)(10))

The South Dakota Department of Agriculture first entered into an enforcement agreement with the Environmental Protection Agency in November 1978, and approved a formal Cooperative Enforcement Agreement in 1985. The South Dakota Department of Agriculture has been granted authority, pursuant to South Dakota Codified Law Chapters 38-20A and 38-21, to administer and carry out legislative intent related to the regulation and use of pesticides. Pursuant to South Dakota Codified Law Chapter 38-21-52, the Department has the authority to enter into cooperative agreements with other agencies. These statutes remain consistent with the intent of FIFRA. The South Dakota Department of Agriculture continues to carry out an efficient and effective pesticide program. The Department plans to conduct routine pesticide use investigations pertaining to the use of pesticides under section 18 emergency exemption registrations. The Department will also respond to all complaints of misuse.

The Minnesota Department of Agriculture will take appropriate steps to ensure that the conditions of this exemption are met.

REPEAT USES(166.20(a)(11))

This request is the first request for the use of Headline SBR/Headline STAR for the control of soybean rust on soybean by all states.

PROGRESS TOWARD REGISTRATION (166.25(b)(2)(ii))

See letters of support **(Appendix B)** for details on the following information:

Pyraclostrobin – BASF has received a Section 3 registration of pyraclostrobin on soybeans in 2004.
See letters of support **(Appendix B – i through B – vi)** for details on the following information:

Tebuconazole – Bayer will be pursuing Section 3 registration of tebuconazole on soybeans following the development and collection of data from residue trials which are underway.

Pyraclostrobin – Data supporting pyraclostrobin use in soybeans were submitted to EPA in March 2003 (PP 3F6581). The use of pyraclostrobin on soybeans was approved and a Section 3 label was issued in December of 2004.

NAME OF PEST (166.20(c)(1))

Scientific Name: *Phakopsora pachyrhizi* H. Sydow and Sydow
Common Name: Australasian soybean rust

ORIGIN OF INTRODUCED PEST (166.20(c)(2))

See text of Master submission

From November 10 to December 1, 2004, Phakopsora pachyrhizi was identified in nine southeastern states in the US. This introduction was presumably associated with Hurricane Ivan moving airborne urediniospores from northern South America in early to mid-September. While it is unknown if the organism will overwinter in the US, this occurrence has shown that the pest will survive and cause disease in the US environment. As such, producers are prepared to treat with fungicides in 2005, should the disease recur. In SD and MN, treatment recommendations will be based on monitoring for the disease in our states as well as reports of the disease elsewhere in the US.

While the overwintering site is not known, it is expected that reintroduction is likely even if the pathogen does not survive the winter in the continental US.

IMPACT OF THE PEST (166.20(c)(3))

See text of Master submission

Projected losses: If soybean rust is introduced to the US late in any given season, losses may be small. However, introduction of the diseases early could be very serious. It is currently not known how the disease would impact markets. The Economic Research Service of USDA has completed an economic analysis of the potential effects of soybean rust entering the US. **(Appendix L)**.

Economic Data From The Past Five Years

The past several years in South Dakota and Minnesota have been full of environmental change. Moisture was plentiful in the early to mid 1990s and in recent years conditions have been drier than normal. Nonetheless, conditions are on average very favorable for the development of soybean rust over most of Minnesota, eastern South Dakota and a large portion of the United States.

Soybean Production.

Table 18: South Dakota statewide soybean production.

Year	Avg. Yield Per Acre (Bushels)*	Average Price Per Bushel*	Gross Revenue Per Acre	Average Costs Per Acre**	Net Revenue Per Acre
1998	38.9	$ 4.60	$ 178.94	$ 163.00	$ 15.94
1999	36.6	$ 4.33	$ 158.48	$ 166.00	($ 7.52)
2000	38.1	$ 4.27	$ 162.69	$ 168.00	($ 5.31)
2001	35.0	$ 4.13	$ 144.55	$ 164.00	($ 19.45)
2002	31.0	$ 5.15	$ 159.65	$ 166.00	($ 6.35)
2003	27.5	$ 6.96	$ 191.40	$ 163.00	$ 28.40
6 yr. Ave.	34.5	$ 4.91	$ 165.95	$ 165.00	$ 0.95

* USDA, http://www.nass.usda.gov:81/ipedb/
**Source: SDSU Economics Department estimate.

Table 19: Minnesota statewide soybean production.

Year	Avg. Yield Per Acre (Bushels)*	Average Price Per Bushel*	Gross Revenue Per Acre	Average Costs Per Acre**	Net Revenue Per Acre
1998	42.0	$ 4.65	$ 195.30	$ 180.33	$ 14.97
1999	42.0	$ 4.42	$ 185.64	$ 170.56	$ 15.08
2000	41.0	$ 4.38	$ 179.58	$ 168.24	$ 11.34
2001	37.0	$ 4.32	$ 159.84	$ 171.35	$ 11.51
2002	43.5	$ 5.25	$ 228.37	$ 165.00	$ 63.37
2003	32.0	$ 7.26	$ 232.32	$ 203.54	$ 28.78
6 yr. Ave.	39.6	$ 5.04	$ 196.84	$ 176.51	$ 20.34

*USDA-National Agricultural Statistics Service, http://www.nass.usda.gov:81/ipedb/
**Source: UMN Department of Applied Economics (http://134.84.17.199/FINBIN/output/20089.htm)

Table 20: United States soybean production.

Year	Avg. Yield Per Acre (Bushels)*	Average Price Per Bushel*	Gross Revenue Per Acre	Average Costs Per Acre**	Net Revenue Per Acre
1998	38.9	$ 4.93	$ 191.78	$ 180.33	$ 11.45
1999	36.6	$ 4.63	$ 169.46	$ 170.56	($ 1.10)
2000	38.1	$ 4.54	$ 172.97	$ 168.24	$ 41.73
2001	39.6	$ 4.38	$ 173.45	$ 171.35	$ 2.10
2002	37.8	$ 5.40	$ 204.12	$ 165.00	$ 39.12
2003	33.9	$ 7.34	$ 248.83	$ 203.54	$ 45.29
6 yr. Ave.	37.4	$ 5.21	$ 194.85	$ 176.51	$ 16.73

* USDA, http://www.nass.usda.gov:81/ipedb/
** MN values used as a reference point - Source: UMN Department of Applied Economics (accessed May 2003 http://134.84.17.199/FINBIN/output/20089.htm and http://www.finbin.umn.edu/CropEnterpriseAnalysis/Default.aspx)

Cost of production data for 16 soybean producing states is available through the National Ag Risk Education Library Budget Section (http://www.agrisk.umn.edu/Default.aspx?Lib=Budget&P=CustomSearch). The cost of soybean production yields near the National average of 38 bu/A, ranged from $99.74 - $346.09 (average $193.18). As such the analysis in **Table 20** reflects a fair estimate of economics of soybean production based on Minnesota cost of production numbers paired with national figures for yield and price. Profitability of the crop has been variable over the past five years and in some locations, such as South Dakota, producers may have been operating at a loss **(Table 18)**, while in Minnesota the crop was more profitable due to greater rainfall **(Table 19)**. Some other states and production systems reported similar losses.

Estimated Revenues For The Site To Be Treated

Costs of fungicides:

- **Labeled products**:

chlorothalonil…… $ 42.00/gal…….. 1.375-2.25 pts/A.. = …… $ 7.20-11.81/A
azoxystrobin…… $ 266.19/gal…… 6.2-15.4 fl oz/A… = …… $ 12.89-32.02/A
pyraclostrobin …… $ 231.00/gal …… 6 - 12 fl oz/A….. = …… $ 10.83 – 21.66/A

- **Proposed Section 18 products:**

propiconazole……...	$ 325.19/gal……	4-8 fl oz/A …….	= ……	$ 10.16 - 20.32/A
tebuconazole ……	$ 335.25/gal……	3-4 fl oz/A……..	= ……	$ 7.85-10.47/A
myclobutanil……..	$ 184.00/gal……	4-8 fl oz/A……..	= ……	$ 5.75-11.50/A
propiconazole + trifloxystrobin ….	$ 150.50/gal……	5.5-10 fl oz/A….	= ……	$ 6.47 - 11.76/A
tetraconazole……	$ 159.00/gal……	13 fl oz/A……	= ……	$ 16.15/A
propiconazole + azoxystrobin ….	$ 112.00/gal……	14-20.5 fl oz/A…	= ……	$ 12.25 - 17.94/A
tebuconazole + pyraclostrobin ….	$ 246.00/gal……	7.8 fl oz/A……	= ……	$ 15.00/A (company estimate)

- **Application and preharvest intervals:**
  tebuconazole + pyraclostrobin…….. at R1 or prior to disease development……..…… 21 day PHI

Soybeans – Estimated Return For Fungicide Application:

Market Price of Soybean $ 4.91/bu (So. Dakota) $ 5.04/bu (Minnesota) *(6-year average)*

Yield Potential 34.5 bu/A (So. Dakota) 39.6 bu/A (Minnesota) *(6-year average)*

1 million Acre Area with Mild to Moderate Severity Soybean rust:

Yield return with use of: propiconazole + azoxystrobin……+ 131% of untreated (Based on one study in Brazil 2004)

Based on best possible yield increases from tebuconazole + pyraclostrobin in Table 1 the treatment advantage over 1 million acres of soybeans under disease pressure from Australasian soybean rust would be $52,510,000 ($52.51 / acre).

Table 21. Fungicide + Application Costs per Application:

Fungicide	Number of Applications*	Product Cost	Application Cost**	Cost of Treatment
tebuconazole + pyraclostrobin	1	$ 15.00	+ $ 3.90 ground application	= $ 18.90
	1		+ $ 5.47 aerial application	= $ 20.47

* Cost of treatment would need to be increased proportionately for multiple fungicide applications.
** 2002 South Dakota Custom Application Rates
(accessed May 2003 http://www.nass.usda.gov/sd/releases/cstmrt00.pdf) – Application cost may be saved in some instances if the fungicide can be tank mixed with a planned herbicide application. No data is available as yet to support the compatibility of any of the fungicide products and herbicides in a soybean system.

It is assumed from the available data that the triazole fungicides and propiconazole + azoxystrobin will perform similarly, that azoxystrobin may provide slightly better control when used preventatively and no data is available for chlorothalonil under these specific criteria. The proposed Section 18 products appear to offer the potential of 23-49 % yield advantage. Estimates will be implemented based on product responses in Paraguay and Zimbabwe trials in 2003-04 where all products were compared side by side. These assumptions and assumptions from the pricing above were used to construct the following table for soybean:

Table 22. Projected return from fungicides

	A	B	C (= A X B)	D	E = C- D
Option	**Expected Yield* /Increase (%) / Increase (bu)**	**Soybean Price†**	**Gross Revenue/A from fungicide (best case)**	**Fungicide Cost + Applic. Cost/A**	**Net Revenue/A±**
azoxystrobin (labeled)	33.1 / 132 / 8.0	$ 5.21	$ 41.68	$ 16.79 – 35.92 $ 18.36 – 37.49	$ 24.87 – 5.76 - $ 23.32 – 4.19
chlorothalonil (labeled)	30.9 / 123 / 5.8	$ 5.21	$ 30.22	$ 10.70 – 15.31 $ 12.67 – 17.20	$ 19.52 – 14.91 – $ 17.55 – 13.02
pyraclostrobin (labeled)	37.4 / 149 / 12.3	$ 5.21	$ 64.08	$ 14.73 – 25.56 $ 16.30 – 28.88	$ 49.35 – 38.52 – $ 47.78 – 35.20
tebuconazole	32.1 / 128 / 7.0	$ 5.21	$ 36.47	$ 11.75 – 14.37 $ 13.42 – 15.94	$ 24.72 – 22.04 $ 23.05 – 20.53
myclobutanil	32.1 / 128 / 7.0	$ 5.21	$ 36.47	$ 9.65 – 15.40 $ 11.22 – 16.97	$ 26.82 – 21.01 $ 25.25 – 19.56
tetraconazole	33.4 / 133 / 8.3	$ 5.21	$ 43.24	$ 20.05 $ 21.62	$ 23.19 $ 20.62
propiconazole	32.1 / 128 / 7.0	$ 5.21	$ 36.47	$ 13.66 $ 15.63	$ 22.81 – $ 20.78
propiconazole + trifloxystrobin‡	31.1 / 124 / 6.0	$ 5.21	$ 31.26	$ 10.37 – 15.66 $ 11.94 – 17.23	$ 20.89 – 15.60 $ 19.32 – 14.03
propiconazole + azoxystrobin	36.6 / 146 / 11.5	$ 5.21	$ 59.91	$ 16.15 – 21.84 $ 17.72 – 23.41	$ 43.76 – 38.07 $ 42.19 – 36.50
tebuconazole + pyraclostrobin¥	32.9 / 131 / 7.8	$ 5.21	$40.64	$ 18.90 $ 20.47	$ 21.74 $ 20.17
Untreated control	25.1 / 0 / (12.3)	$ 5.21	$ (64.08)	N/A	($ 64.08)

* Based on fungicide response in Paraguay and Zimbabwe USDA trial in 2003-2004 – adjusted to a 37.4 bushel per acre soybean yield (mean US soybean yield for past six years) – 37.4 bu/A less optimal yield response equals 25.6 bu/A (estimated untreated yield)
† Based on mean US market price from past six years
± Based on a single application at the low and high rate applied by ground and/or air
‡ Based on only Paraguay locations – not included in Zimbabwe trials
¥ Based on yield response in one Brazillian study in 2004.

Therefore, we can see a comparable advantage to the triazole products relative to azoxystrobin (if applied at low rates), while allowing greater product availability to address a potential epidemic. In fact the economics of a decision to use a high rate of azoxystrobin, which is preferred for longer residual, more effective disease control and better fungicide resistance management, offer only about half the advantage of using a triazole or pre-blended product such as Stratego or Quilt. Obviously, the lower priced products have a greater likelihood of economic return when two applications are used, particularly if prices are depressed.

Comparison of estimated revenue in treating with Headline SBR/Headline STAR *vs.* Quadris (estimates*) assuming 1 million acres treated:

Estimated cost of treatment (1 million soybean acres x $ 16.79/acre) using azoxystrobin = $ 16.8 million
Estimated cost of treatment (1 million soybean acres x $ 15.00/acre) using
Headline SBR/Headline STAR = $ 15.0 million
advantage with Headline SBR/Headline STAR: = $ 1.8 million

The above economic analysis does not reflect the benefit of reducing risk of resistance to strobilurin chemistry.

* Variablilty in the relative paucity of available data causes need for estimation of potential efficacy of products. Depending on disease pressure and production environment, some applications have been very efficacious while at other locations and in different environments, other product have performed better.

APPENDICES

A …..…… List of members of Technical Science Working Group on Soybean Rust

B …..…… Letters of Support and Draft Labels from registrants, and support from the Triazole Task Force

- **B – i …….. Supporting documents for propiconazole**
- **B – ii …….. Supporting documents for tebuconazole and propiconazole + trifloxystrobin**
- **B – iii …….. Supporting documents for myclobutanil**
- **B – iv …….. Supporting documents for tetraconazole**
- **B – v …….. Supporting documents for pyraclostrobin + boscalid**
- **B – vi …….. Supporting documents for pyraclostrobin**
- **B – vii…….. Supporting documents for propiconazole + azoxystrobin**
- **B – viii……. Supporting documents for tebuconazole + pyraclostrobin**

C ..…… Possible models of spread for Australasian soybean rust

D ..…… Bioterrorism Act

E ..…… Guidelines from NA-FRAC (North American Fungicide Resistance Action Committee) for the avoidance of developing fungicide resistant biotypes of plant pathogenic fungi.

F ..…… Supporting Documents on the Potential Severity of Soybean Rust

G ..…… USDA Strategic Plan to Minimize the Impact of the Introduction and Establishment of Soybean Rust on Soybean Production in the United States

H ……... Report from USDA Studies on Fungicide Efficacy in Controlling Soybean Rust in Brazil and Paraguay, 2002-2003

H – ii …….Report from USDA Studies on Fungicide Efficacy in Controlling Soybean Rust in Brazil and Paraguay, 2003-2004

I ……... Dow residue studies conducted in Brazil on myclobutanil on soybeans

J …… Preliminary Report from the Triazole Task Force

K …… Federal List of Endangered and Threatened Species

L …… Original and Revised / Updated Economic Analysis