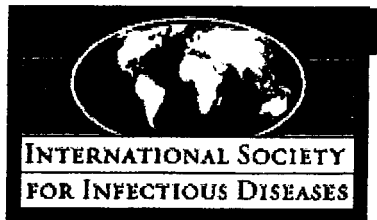


医薬品 研究報告 調査報告書

識別番号・報告回数		報告日 2005年4月20日	第一報入手日 2004年10月18日	新医薬品等の区分 該当なし	厚生労働省処理欄
一般的名称		研究報告の公表状況	2004年9月16日のフランス食品安全局の報告	公表国 フランス	
販売名(企業名)	タココンプ (ZLB ベーリング株式会社)				
研究報告の概要	問題点 (南部フランスにおけるウエストナイルウイルス(WNV)流行) 2004年8月28日(疫学第35週)に、ウマ2頭のWNV感染疑い(臨床診断)例が、フランス南東部 Camargue 地域で獣医師により確認された。 これらのウマから採取された血液検体のELISA法による検査室診断が、食品安全機関 Agence Francaise de Securite Sanitaire des Aliments により実施され、抗WNV IgM抗体およびIgG抗体が9月10日に検出された。同国政府当局には、9月13日に警報が送られた。 9月30日(疫学第40週)までに、ウマでの死亡症例(安楽死処分例を含む)4頭と疑い症例37頭が報告された。検査実施されたウマ18頭中14頭が、WNV陽性(WNV特異的IgM抗体検出またはRT-PCR法陽性)であった。最も共通して認められた臨床症状は、発熱、衰弱、食欲不振、運動失調、麻痺、過敏性である。Lyonのアルボウイルス委託検査センターThe Centre National de Reference des Arbovirus では、3頭のウマでWNV特異的中和抗体価の上昇(PRNT80抗体価>160倍)を認めた。				使用上の注意記載状況・その他参考事項等
	報告企業の意見	今後の対応			
タココンプの原料のウマコラーゲンがフランスのウマ腱より製造されているので、製造元に安全性を確認した。 タココンプに関してWNVの不活化データはないが、パラインフルエンザウイルスタイプ3およびWNVと同じenveloped RNAウイルスを用いてpH処理とγ線照射による不活化試験を実施している。 両処理とも、パラインフルエンザウイルスタイプ3は検出限界以下で不活化された。 pH treatment (pH 3.2, 18 h, 18 ° C): Reduction/Clearance factor [log10] > 5.9 gamma irradiation (25.1 kGy): Reduction/Clearance factor [log10] > 4.0 実際の製造工程ではenveloped ウイルスに対してLRF (log10 reduction factor) 4以上の2つのウイルス除去工程が含まれる。全工程でLRFが平均10以上ある。さらにウマ腱のウイルス濃度は、血液や血漿と比較して低値であると考えられる。 以上より、タココンプのウマコラーゲンは安全であると考えられる。		今後とも感染症に関する情報収集に努める所存である。			



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Subject PRO/AH/EDR> West Nile virus, equines - France (Camargue) (02)

WEST NILE VIRUS, EQUINES - FRANCE (CAMARGUE) (02)

A PromED-mail post
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West Nile outbreak in horses in southern France: Sep 2004

On 28 Aug 2004 (week 35), 2 suspected clinical cases of West Nile virus (WNV) infection in horses were identified by veterinarians in Saintes-Maries de la Mer, in the Camargue region of south eastern France. Enzyme linked immunosorbent assay (ELISA) tests were performed on blood specimens from these horses by the Agence Francaise de Securite Sanitaire des Aliments (the French food safety agency), and WNV IgM and IgG antibodies were detected on 10 Sep 2004. An alert was sent to the national authorities on 13 Sep 2004.

By 30 Sep 2004 (week 40), 37 suspected cases in horses, including 4 fatalities or euthanasia, were reported. 14 of the 18 horses tested were positive for WNV (WNV IgM detection or positive RT-PCR (reverse transcriptase polymerase chain reaction)). The most common clinical symptoms were fever, prostration, anorexia, ataxia, paresis, and irritability. The Centre National de Reference des Arbovirus (National Reference Centre for arboviruses) in Lyon confirmed the presence of specific neutralising antibodies in 3 cases (PRNT80 titre >160).

The suspected cases were distributed over an area extending about 35km west and north from the initial focus, Saintes-Maries de la Mer. Saintes-Maries de la Mer is situated in the Rhone delta, where migrating and resident birds are numerous. The infected area covered approximately the same region where a previous WNV outbreak in horses occurred in 2000 (131 suspected cases/76 confirmed cases from late August until early November) [1]. No human cases were reported in 2000 and none in 2004 by week 39.

After the 2000 outbreak, an integrated programme of WNV surveillance involving partners from the Ministries of Agriculture, Public Health and the Environment, as well as local agencies, was initiated. It covered 3 Departements: Herault, Gard and Bouches du Rhone [2]. Sentinel birds (chicken and ducks) were tested for WNV antibody detection on a regular basis. Suspected cases in horses and humans were tested for WNV infection.

Dead wild birds were collected for WNV testing. Because of the limited WNV outbreak in Frejus (in the Var department, 200 km east of the Camargue) in 2003 which involved 7 human cases (3 encephalitis and 4 cases of febrile illness) and 4 equine cases, the 2004 sentinel bird surveillance programme was extended along the Mediterranean coast to cover 6 Departements from the

eastern Pyrenees to the Var, as well as the report of suspected cases in humans and horses [3].

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A low level of WNV activity was reported in the Camargue region in sentinel birds: one seroconversion in 2001, one in 2002 and none in 2003. In late July 2004, a WNV seroconversion was reported in a sentinel chicken from Saintes-Maries de la Mer, and a second seroconversion was reported in mid-August at the same location. On 6 Sep 2004, 2/3 of the sentinel birds from this flock were positive for WNV antibodies. A sentinel duck was reported to be positive for WNV on 16 Aug (infection confirmed on 7 Sep 2004) in Saint-Just, Herault.

Following the alert on 13 Sep several measures were taken: (a) Increased surveillance for detection of suspected cases in human and equine populations; (b) entomological studies at areas where infected horses have been found; (c) a restriction on blood donations from individuals living in or with history of travel to the infected area until the end of October 2004. An absence of WNV viral genome was reported in a retrospective study on 789 blood donations collected from donors in the infected region from the beginning of August 2004 to mid-September.

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(3) Mailles A, Dellamonica P, Zeller H, Durand JP, Zientara S, Goffette R et al. Human and equine West Nile virus infections in France, August-September 2003. *Eurosurveillance Weekly* 2003; 7(43): 23/10/2003
<http://www.eurosurveillance.org/ew/2003/031023.asp#1>

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{see also:

West Nile virus, equines - France (Camargue)	20040929.2693

2003	

West Nile virus, human, equine - France: susp.	<u>20031011.2559</u>
2001	

West Nile virus, horses - France	<u>20010113.0103</u>
2000	

West Nile virus, horses - France (04)	<u>20001012.1743</u>
West Nile virus, horses - France (03)	<u>20000915.1585</u>
West Nile virus, horses - France (02)	<u>20000914.1572</u>
West Nile virus, horses - France	<u>20000912.1561</u>]

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